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In The Supreme Court of the United States

ESTATE OF MARION LANDERS,
as represented by its executor, Richard Landers,
MARION A. DIXON, and MURIEL GRIGLEY,
on behalf of themselves and all others similarly situated,

Petitioners,

v.

KATHLEEN SEBELIUS, Secretary of the
Department of Health and Human Services,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

PETITION FOR A WRIT OF CERTIORARI

GILL DEFORD*
JUDITH A. STEIN
BRAD S. PLEBANI
WEY-WEY KWOK
CENTER FOR MEDICARE ADVOCACY, INC.
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790

TOBY S. EDELMAN
CENTER FOR MEDICARE ADVOCACY, INC.
1025 Connecticut Ave., N.W., Suite 709
Washington, DC 20005
(202) 293-5760

Attorneys for Petitioners

**Counsel of Record*

May 2009

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTIONS PRESENTED

Medicare coverage of skilled nursing care is conditioned on the beneficiary's prior hospitalization for at least three days as an "inpatient." The intermediary's manual interprets "inpatient" to include only the period after formal admission, thereby excluding days in the emergency room and on observation status. The court of appeals accepted the manual's interpretation. The questions presented are:

1) Whether the failure of the court of appeals to employ traditional canons of statutory construction, while instead citing only dictionary definitions of "inpatient," conflicts with this Court's directives for determining the intent of Congress.

2) Whether the court of appeals misapplied the *Skidmore* standard because of the lack of clarity and consistency with which that standard has been analyzed and applied.

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INTRODUCTION

Petitioners Estate of Marion Landers (as represented by its executor Richard Landers), Marion A. Dixon, and Muriel Grigley, on behalf of themselves and the nationwide class of Medicare beneficiaries whom they represent, respectfully petition this Court for a writ of certiorari to review a decision of the United States Court of Appeals for the Second Circuit. In the context of an eligibility condition that prevents elderly and disabled Medicare beneficiaries throughout the country from obtaining continued care after hospitalization, the decision raises two crucial issues of statutory construction.

First, this Court has held that, in determining whether the intent of Congress is clear, courts should not rely solely on specific statutory language, but, rather, on the "traditional tools of statutory construction." *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n. 9 (1984). The court of appeals, however, ignored that directive, finding ambiguity merely in the lack of a consistent dictionary definition of one word. Second, the court below was confounded by the lack of clear direction in applying *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), with the result that it deferred to a manual provision that even the respondent Secretary has speculated may not fulfill the intent of Congress. Because of the conflict on the first point and the need for significant clarification in the *Skidmore* context, this Court should grant the petition to ensure that hospitalized Medicare beneficiaries are not deprived

of the skilled nursing care that Congress intended for them.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Second Circuit is reported at 545 F.3d 98 (2008) and is reproduced in the Appendix at App. 1. The opinion of the United States District Court for the District of Connecticut, from which the appeal was taken, is reported at 2006 WL 2560297 (2006) and is reproduced at App. 31. The opinion of the district court certifying the case as a nationwide class action, which was not at issue in the appeal, is reported at 232 F.R.D. 42 (2005). The Second Circuit's unreported Order and Corrected Order, denying the petition for rehearing and rehearing en banc, are reproduced at App. 67 and App. 69, respectively.

JURISDICTION

The judgment of the court of appeals was entered on October 1, 2008. Petitioners timely filed a petition for rehearing or rehearing en banc on November 3, 2008. The court of appeals denied the petition on February 11, 2009, App. 67, and issued a Corrected Order denying the petition on February 17, 2009. App. 69. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PROVISIONS INVOLVED

Statutory provisions

42 U.S.C. § 1395d. Scope of benefits

(a) Entitlement to payment for inpatient hospital services, post-hospital extended care services, home health services, and hospice care

The benefits provided to an individual by the insurance program under this part shall consist of entitlement to have payment made on his behalf . . . for –

(1) inpatient hospital services or inpatient critical access hospital services for up to 150 days during any spell of illness . . . ;

(2)(A) post-hospital extended care services for up to 100 days during any spell of illness . . . ;

* * * *

42 U.S.C. § 1395x. Definitions

For purposes of this subchapter –

* * * *

(b) Inpatient hospital services

The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital –

(1) bed and board;

(2) such nursing services and other related services, such use of hospital

facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

* * * *

(i) Post-hospital extended care services

The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer.

* * * *

42 U.S.C. § 1395ww. Payments to hospitals for inpatient hospital services

(a) Determination of costs for inpatient hospital services; limitations; exemptions; "operating costs of inpatient hospital services" defined

* * * *

(4) For purposes of this section, the term "operating costs of inpatient hospital services"

. . . includes the costs of all services for which payment may be made under this subchapter that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days . . . immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary).

* * * *

Regulation

42 C.F.R. § 409.30 Basic requirements.

* * * *

(a) *Pre-admission requirements.* The beneficiary must

(1) Have been hospitalized in a participating or qualified hospital or participating CAH [critical access hospital], for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge;. . . .

* * * *

Manual provision

Centers for Medicare & Medicaid Services, Publ'n No. 100-02, *Medicare Benefit Policy Manual*, ch. 1, § 10

* * * *

> An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
>
> * * * *

STATEMENT OF THE CASE

A. Medicare Coverage of "Post-Hospital Extended Care Services"

As a component of Medicare's hospital benefit, coverage of "post-hospital extended care services" is available to eligible beneficiaries. 42 U.S.C. § 1395d(a)(2)(A). The legislative intent of covering this care in a skilled nursing facility (SNF) after hospitalization was to provide "a less expensive alternative to what would otherwise be the final, convalescent portion of an acute care stay of several days as an inpatient at a hospital." 70 Fed.Reg. 45,026, 45,051 (Aug. 4, 2005); 70 Fed.Reg. 29,070, 29,099 (May 19, 2005); see also S. Rep. No. 89-404, 89th Cong., 1st Sess. (1965), *reprinted in* [1965] U.S.C.C.A.N. 1943, 1971.

The statute conditions coverage of this post-hospital care on the patient having spent at least

"3 consecutive days" in the hospital prior to transfer to the SNF. 42 U.S.C. § 1395x(i). As the respondent Secretary has explained, this three-day qualifying stay requirement is a condition of eligibility intended "to target the SNF benefit more effectively at the limited segment of the nursing home population that the benefit was actually designed to cover. . . ." 70 Fed.Reg. at 29,099.

The statute describes the patient's stay in the hospital as that of an "inpatient," 42 U.S.C. § 1395x(i), but it does not define that term. The relevant regulation also does not provide a definition. See 42 C.F.R. § 409.30(a)(1). The only definition of "inpatient" appears in the Secretary's manual for guidance to the intermediaries that process claims and to the providers of services. Centers for Medicare & Medicaid Services, Publ'n No. 100-02, *Medicare Benefit Policy Manual*, ch. 1, § 10, *available at* http://www.cms.hhs.gov/Manuals/IOM/list.asp. It states that "[g]enerally, a person is considered an inpatient if formally admitted as inpatient. . . ." This definition of "inpatient" thus imposes a further condition of eligibility for coverage of the post-hospital care, namely, that the three days of hospitalization must come after the patient is formally admitted. Consequently, time spent prior to formal admission, either in the emergency room or on observation status, is not counted.[1]

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[1] The day of discharge is not counted towards the three days. 42 C.F.R. § 409.30(a)(1).

The three-day rule has been in the statute since Medicare's inception in 1965, but the Secretary has never subjected the definition of "inpatient" to notice-and-comment rulemaking. After this litigation was commenced, she requested comments on whether time spent in observation status should be counted, noting that "over time, practice and treatment of observation status may have changed." 70 Fed.Reg. at 29,099. Although acknowledging that most commentators supported counting that time towards the qualifying period, the Secretary continued to decline to act because she was "not yet ready to make a final determination at this time." 70 Fed.Reg. at 45,050.

The Secretary's inaction is noteworthy because of the great changes that have taken place in hospital practices since the Medicare statute was enacted. At that time, observation status did not exist. 70 Fed.Reg. at 29,099. It is now in regular use, and in fact is frequently abused, with patients sometimes spending two or more days on observation status. Although observation status is billed as outpatient, the same care and services are provided whether the patient is on observation status or has been formally admitted: "[T]he distinction between inpatient and extended outpatient observation represents a difference in billing, not a difference in medical treatment." Administrative Consultant Service, LLC, *Appropriate Use of Observation Bed*, 5, 8 (Jan. 2009), *available at* http://www.acsteam.net/newsletters/MedObNews0109.pdf. At the same time, more patients have been forced to "board" in ERs: "These patients remain in the

emergency department after the decision has been made to admit them to the hospital. . . ." Government Accountability Office, *Hospital Emergency Departments: Crowded Conditions Vary Among Hospitals and Communities*, GAO-03-460, at 8 (March 2003), *available at* http://www.gao.gov/new.items/d03460.pdf.

The consequence of these and other developments has been a dramatic reduction in the time that patients are hospitalized.[2] Despite the resulting impact on the ability of beneficiaries to qualify under the three-day rule, the Secretary declined to reconsider her position.

B. Proceedings Prior to and in the District Court

Each of the three petitioners, Marion Landers (now deceased), Marion Dixon, and Muriel Grigley, was taken to the emergency room of a hospital in the evening. Ms. Landers and Mr. Dixon were put on observation status after midnight of the evenings on which they arrived, and later were formally admitted to the hospital. Ms. Grigley was formally admitted

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[2] From 1970 to 2004, the average hospitalization time for people age 65 and over decreased by 55%, from 12.6 days to 5.6 days. Centers for Disease Control and Prevention, *2001 National Hospital Discharge Survey*, No. 332 at 1 (Apr. 9, 2003), *available at* http://www.cdc.gov/nchs/data/ad/ad332.pdf; Centers for Disease Control and Prevention, *2004 National Hospital Discharge Survey*, No. 371 at 10, Table 4 (May 4, 2006), *available at* http://www.cdc.gov/nchs/data/ad/ad371.pdf.

shortly after midnight of the evening of her arrival without having first been put on observation status. All three were discharged on the fourth calendar day of their hospitalizations and transferred to a SNF. Since at least one of their calendar days of hospitalization was pre-formal admission and the day of discharge was not counted, however, none of the three patients met the three-day qualifying stay rule.

Petitioners' timely requests for administrative review of the denials of Medicare coverage for their SNF stays were followed by this federal court challenge. They invoked the district court's jurisdiction under the federal question statute, 28 U.S.C. § 1331, the mandamus statute, 28 U.S.C. § 1361, and the Social Security Act review provision as applied to Medicare cases, 42 U.S.C. § 1395ff(b)(1)(A) (incorporating 42 U.S.C. § 405(g)). The district court determined that, since it had jurisdiction pursuant to the Social Security Act review provisions, federal question and mandamus jurisdiction were not available as grounds for review. App. 35-39.

The district court certified a nationwide class, represented by the three petitioners, of Medicare beneficiaries whose coverage for post-hospital care had been or would be denied despite their having been hospitalized for at least three days. *Landers v. Leavitt*, 232 F.R.D. 42, 48-49 (D.Conn. 2005). Membership in the class extends back to September 24, 2004.

On cross-motions for summary judgment, the district court held that the statute was ambiguous. App. 46-47. Applying its view of the standard outlined in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), the court upheld the Secretary's interpretation of "inpatient." App. 47-63.

C. Court of Appeals Proceedings

A two-judge panel of the Second Circuit affirmed.[3] Applying the two-step approach dictated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court first concluded that the statute was ambiguous, App. 9, and then proceeded to determine the appropriate level of deference. Relying on the fact that the non-legislative interpretation was the product of an agency manual, the Second Circuit rejected "*Chevron* deference," but, employing its understanding of *Skidmore*, the court found the agency's interpretation acceptable. *Id.* at 10-23.

First, the court viewed the interpretation to be "longstanding." *Id.* at 15-16. Second, the panel believed the Secretary's position to be consistent. *Id.* at 16. It rejected the significance of the petitioners' point that pre-formal admission time in the hospital was treated as part of an inpatient stay for *hospital*

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[3] After the third panel member recused himself, the remaining members decided the appeal in accordance with Second Circuit rules. See App. 1 & n. *.

coverage, while the same time was not considered inpatient for purposes of the *SNF* coverage. The court reached this conclusion despite expressing some doubt as to whether this differential treatment of the same time in the hospital was "sensible as a policy matter." *Id.* at 18.

Third, the court relied on the fact that the Secretary had sought comments on whether the increasing use of observation status should alter her interpretation. *Id.* at 18-20. While observing that the Secretary's "statement with respect to observation status may be less than wholly satisfying," *id.* at 20, the panel viewed this as a reconsideration "on the public record" and therefore relevant. *Id.* at 18.

Fourth, relying on Second Circuit case law, the court stated that the manual provision was entitled to "an intermediate level of deference that lies between a published recommendation and an interpretation advanced only in litigation." *Id.* at 23 (citation and internal quotation marks omitted).

In addition, the court found unpersuasive or irrelevant to its *Skidmore* analysis petitioners' arguments based on the definition of "inpatient hospital services" in 42 U.S.C. § 1395x(b) and the fact that five circuit courts had rejected the Secretary's interpretation of the word "inpatient" in the context of 42 U.S.C. § 1395x(a)(2). App. 23-25.[4]

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[4] The lower courts also rejected petitioners' contentions on issues not presented by this petition. See App. 26-30, 35-42, 64-65.

Petitioners timely filed for rehearing or rehearing en banc. Prior to ruling on that petition, the court of appeals issued a revised opinion that made a slight modification to an aspect of the decision not here at issue. On February 11, 2009, the court denied the petition for rehearing or rehearing en banc. App. 67. Since that order mistakenly stated that "Appellant Michael O. Leavitt" had filed the petition for rehearing or rehearing en banc, the court issued a corrected order on February 17, 2009 in which the petitioners were correctly listed as having filed the petition. *Id.* at 69.

With the petition denied, the panel's conclusions that the intent of Congress was ambiguous and that the respondent's interpretation was persuasive under the *Skidmore* standard became final.

REASONS FOR GRANTING THE WRIT

I. The Second Circuit's Failure to Employ the Traditional Tools of Statutory Construction Conflicts with This Court's Directives for Determining the Intent of Congress.

This case is of great importance to Medicare beneficiaries nationwide. By definition, every individual affected by the interpretation at issue has recently suffered a serious illness or injury requiring hospitalization and is in need of skilled nursing care to continue his or her rehabilitation or convalescence.

As the Secretary has noted, Congress recognized the need for this "continuation of an acute hospital stay" and wove it into the hospitalization benefit. 70 Fed.Reg. at 29,099; see 42 U.S.C. §§ 1395d(a)(1), (2). The Secretary has also observed, though, that the manual's interpretation may undermine this congressional intent: "[T]he effect of not counting this observation time under the existing policy ultimately might be to restrict SNF coverage to a narrower segment of the beneficiary population than the Congress originally intended." 70 Fed.Reg. at 29,099.

Despite the critical importance of ascertaining congressional intent in this context, however, the court of appeals gave scant attention to that effort. Rather than carefully evaluating the factors relevant to discerning intent at "*Chevron* Step One," the panel declared that it "ha[d] little difficulty finding ambiguity here." App. 9. It supported that conclusion by noting that "inpatient" was not defined in the statute and that dictionary definitions of the word were sufficiently variable that they could sustain either position. *Id.*

The use of dictionary definitions as the sole source for determining congressional intent runs contrary to this Court's admonition: "If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." *Chevron*, 467 U.S. at 843 n. 9. The court below, however, viewed its task as merely to ascertain the meaning of one word. Finding no

clear-cut answer to that inquiry, it decreed the language ambiguous and moved on to "*Chevron* Step Two." App. 8-9.

This Court has consistently restated its *Chevron* holding that a court's task at Step One is not only to parse individual words and phrases but to determine the intent of Congress through the canons of construction: "In determining whether Congress has specifically addressed the question at issue, a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning – or ambiguity – of certain words or phrases may only become evident when placed in context." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); see also, *e.g.*, *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990); *NLRB v. United Food & Commercial Workers Union*, 484 U.S. 112, 123 (1987). A court is not free to declare ambiguity merely by noting varying dictionary definitions for one word in the statutory scheme.

The elements of statutory construction are well established. They include analyzing the statutory language itself, the specific context in which the words are used and the broader context of the statute as a whole, the structure and purpose of the statute, and the statute's legislative history. See, *e.g.*, *Zuni Public School Dist. No. 89 v. Dep't of Education*, 550 U.S. 81, 90 (2007); *Hibbs v. Winn*, 542 U.S. 88, 101 (2004); *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133; *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281,

291 (1988); *INS v. Cardoza-Fonseca*, 480 U.S. 421, 449 (1987); *accord*, *Chevron*, 467 U.S. at 845-853 (discussing the legislative history at length to discern the intent of Congress).

The Second Circuit's failure to follow these enshrined tenets was not harmless error. First, although the word "inpatient" in 42 U.S.C. § 1395x(i) is not explicitly defined, the statute does state that "[t]he term 'inpatient hospital services' means the following items and services furnished to an inpatient of a hospital. . . ." 42 U.S.C. § 1395x(b). Receiving "inpatient hospital services" is thus the hallmark of inpatient status, as the Second Circuit noted in another Medicare case: "[T]he meaning of 'inpatient' necessarily implicates the nature of the services received. . . ." *Levi v. Heckler*, 736 F.2d 848, 850 (2d Cir. 1984). Since the care received while on observation status is the same as that received after formal admission, "inpatient" cannot be limited to the period after formal admission.[5]

Moreover, the specific context of the SNF care at issue dictates a broader meaning for "inpatient." Coverage of that care – the "post-hospital extended care services" – is only one element of a continuum of coverage for hospitalized beneficiaries. The SNF care is, literally, an extension of the hospitalization itself,

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[5] The court below did discuss 42 U.S.C. § 1395x(b) but not in the context of discerning congressional intent at Step One. See App. 23-24.

and its coverage is therefore codified as an element of the overall hospital coverage. See 42 U.S.C. §§ 1395d(a)(1), (2). The goal was to "target SNF coverage to individuals requiring a short-term, fairly intensive stay in a SNF *as a continuation of an acute hospital stay*." 70 Fed.Reg. at 29,100 (emphasis added). In that context, it is illogical to use the date of formal admission, which occurs at an arbitrary point along the spectrum of a given hospitalization, to deprive beneficiaries of the coverage needed to complete treatment necessitated by the acute event.

Another relevant contextual aspect informing the meaning of "inpatient" is that pre-admission time is treated as inpatient for the purposes of hospital coverage. 42 U.S.C. § 1395ww(a)(4). Thus, under the Secretary's interpretation of "inpatient," the same time in the hospital is evaluated differently depending on whether the coverage at issue is for SNF care or for hospital care. It is inconceivable that Congress would have intended the undefined term "inpatient" not to encompass pre-admission time for purposes of SNF coverage when it directed that the same pre-admission time be treated as inpatient time for hospital coverage purposes.

The legislative history also offers insight. In discussing the purpose of the three-day rule, the Senate Finance Committee used language indicating a less restrictive interpretation than appears in the manual: "The posthospital extended care benefits which would be provided under the hospital insurance plan would cover care in qualified extended

care facilities where the patient was *hospitalized* for 3 or more consecutive days. . . ." S. Rep. No. 89-404, 89th Cong., 1st Sess. (1965), *reprinted in* [1965] U.S.C.C.A.N. 1943, 1971 (emphasis added).

Finally, it is a "general principle that the Social Security Act should be broadly construed, so as to carry out Congress's intent to provide medical expense coverage for all qualifying individuals." *Mayburg v. Secretary of Health & Human Services*, 740 F.2d 100, 103 (1st Cir. 1984) (Breyer, J.) (citations omitted). As the Second Circuit recognized in rejecting the Secretary's interpretation of "inpatient" in the related SNF context: "To allow Medicare eligibility to turn on these factors is not only illogical but also contrary to the spirit of the Social Security Act." *Levi*, 736 F.2d at 849-50; see also, *e.g.*, *Mayburg*, 740 F.2d at 103 (in another decision rejecting the same interpretation, the Secretary's view of "inpatient" is termed a "curious anomaly"). The remedial purposes of Medicare and a presumption in favor of a rational reading of its implementing statute preclude interpreting "inpatient" to terminate coverage for hospitalized patients in the midst of recovery, who were precisely the intended beneficiaries of the post-hospital extended care benefit.

The court of appeals' refusal to employ the traditional tools of statutory construction warrants review to effect the congressional intent of covering the entire range of care necessary to respond to an acute episode.

II. The Second Circuit's Application of the *Skidmore* Standard Illustrates the Lack of Guidance Available to the Lower Courts When *Chevron* Deference Is Not Appropriate.

The portion of the court of appeals' decision applying the *Skidmore* standard presents a different reason for this Court's review. As is true of the first question presented, the panel's resolution flows from a flawed analysis. The reason for that error, however, lies not in the lower court's deviation from this Court's dictates, but rather, with all due respect, in the lack of consistent guidance from this Court.

The importance of *Skidmore* to judicial review of agency interpretations cannot be underestimated. Since its revival in *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) and *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001), *Skidmore* has become "the baseline deference standard." Kristin E. Hickman and Matthew D. Krueger, *In Search of the Modern* Skidmore *Standard*, 107 Colum. L. Rev. 1235, 1246 (2007) [hereinafter, Hickman and Krueger]. This Court has provided little direction, however, as to "how lower courts should apply the *Skidmore* standard," and, in particular, what factors the courts should employ and "how these factors relate to each other or whether certain factors are more important than others." *Id.* at 1237, 1257 (footnote omitted).

In *Christensen* the Court summarized the *Skidmore* standard by stating that interpretations may be "'entitled to respect' . . . but only to the extent that those interpretations have the 'power to persuade.'" *Christensen*, 529 U.S. at 587 (quoting *Skidmore*, 323 U.S. at 140). The Court has also listed various specific considerations that are sometimes cited to define the *Skidmore* standard. *Skidmore* itself noted "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." 323 U.S. at 140. In *Mead*, in addition to quoting the *Skidmore* language of the previous sentence, 533 U.S. at 228, this Court described relevant factors as "the degree of the agency's care, its consistency, formality, and relative expertise, and . . . the persuasiveness of the agency's position," *id.* (footnotes and citation omitted), and also cited "thoroughness, logic and expertness, [the interpretation's] fit with prior interpretations, and any other sources of weight." *Id.* at 235; see also, *e.g.*, *Gonzalez v. Oregon*, 546 U.S. 243, 268-69 (2006) (quoting *Skidmore* and *Mead* for a list of factors).

Despite specifying these various considerations for the *Skidmore* analysis, though, the Court does not always apply them. See, *e.g.*, *Raymond B. Yates, M.D., P.C. Profit Sharing Plan v. Hendon*, 541 U.S. 1, 18 (2004) (citing *Skidmore* but not applying the factors); *Clackamas Gastroenterology Associates, P.C. v. Wells*, 538 U.S. 440, 449 & n. 9 (2003) (same).

The result of these varying messages is to leave the lower courts with insufficient direction for evaluating agency interpretations not subject to *Chevron* deference: "[T]he overarching impression that one receives from the *Skidmore* cases is a lack of uniformity in how courts apply the sliding-scale conception of *Skidmore*." Hickman and Krueger, 107 Colum. L. Rev. at 1281. The decision below illustrates the difficulty of applying the *Skidmore* standard as presently outlined. Although the panel quoted some of the *Mead* and *Skidmore* language for the factors that could be considered, App. 14, it then examined four somewhat different considerations, while terming them "the *Skidmore* factors" (*id.* at 14, 23): the longstanding duration of the interpretation, the consistency of the interpretation, the Secretary's public reconsideration of her position in 2005, and the relative formality of the interpretation. *Id.* at 15-23. The court did not cite *Skidmore, Christensen*, or *Mead* as providing the authority for these specific considerations.

Although this Court has considered a policy's longevity to be relevant in the context of *Chevron* deference, see, *e.g.*, *Barnhart v. Walton*, 535 U.S. 212, 220, 222 (2002) (relying on the longstanding duration of the policy in a case where "*Chevron* provides the appropriate legal lens"), the Court did not engraft that consideration onto the *Skidmore* standard through either *Skidmore* or *Mead*. Furthermore, the interpretation's consistency, which the court of appeals cited as the second *Skidmore* factor, primarily

represents a semantic variation on the longstanding duration analysis. See App. 16.[6]

The third factor cited below was the agency's belated decision to seek public comment on the interpretation – for the first time in its 40-year existence and shortly after this litigation commenced. *Id.* at 18. The court rejected petitioners' contention that the Secretary acted only to give the appearance of requesting public input, *id.* at 21-22, and, with no reliance on *Skidmore* or *Mead*, the court decreed that the Secretary's decision not to take corrective action was "not so deficient that it lacks persuasive force." *Id.* at 20-21.

Finally, the panel relied on the "relatively formal" nature of the interpretation to invoke a Second Circuit rule that a manual provision "merit[s] an 'intermediate level' of deference." *Id.* at 22, 23 (quoting *Rabin v. Wilson-Coker*, 362 F.3d 190, 198 (2d Cir. 2004)). The court did not explain, however, why a statement buried for decades in a multi-volume manual for intermediaries was automatically entitled

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[6] The court of appeals rejected petitioners' contention that the longevity of the agency's interpretation actually rendered its position *less* persuasive because the Secretary had failed to alter the policy in the face of dramatically changed conditions, especially the increasing use of observation status and the decline in the length of hospitalizations (discussed *supra* at 8-9). App. 21. See, *e.g.*, *Detsel v. Sullivan*, 895 F.2d 58, 64 (2d Cir. 1990) ("[A]gencies must interpret their regulations in light of changing circumstances, particularly in areas characterized by rapid technological development.").

under *Mead* or *Skidmore* to some degree of heightened deference.

Thus, the decision below mentions two considerations that have been identified as possible *Skidmore* factors, consistency and formality. For neither of these, however, or for the other cited considerations (which have not been noted as *Skidmore* factors), does the decision provide a rationale as to why they, alone or together, render the interpretation persuasive. Nor does the decision offer any insight as to why *Skidmore* dictates that resolution, or why other *Skidmore* factors were not considered. The panel noted that the Secretary's explanation "may be less than wholly satisfying," App. 20, and questioned whether it was "sensible as a policy matter" to treat pre-admission time differently for hospital coverage and SNF coverage. *Id.* at 18. Nevertheless, the court determined that the "interpretation is entitled to a great deal of persuasive weight." *Id.* at 14-15.

No rationale for this conclusion was offered. The court referred to the *Skidmore* factors and listed some of them, but for the most part it simply recited some points that, without analysis, weighing, or balancing, rendered the Secretary's interpretation acceptable in the panel's view. For the court below, the *Skidmore* standard was an empty vessel into which it could pour whatever considerations it deemed relevant.

In any case, but especially one where health care for the nation's most vulnerable population is at stake, the lower courts need clear guidance on the

standards for evaluating the propriety of an agency's nonlegislative interpretation. With the growing importance of the *Skidmore* standard, the courts must know what factors to consider and not to consider, what weight to give each of those factors, and how to balance and compare them.

For the present, this Court has announced the existence of a standard, the circumstances for its application, and several potentially relevant considerations. Beyond that, however, little guidance exists to direct the lower courts' application of the standard. Review of the decision below is warranted to bring clarity to the area.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

GILL DEFORD
(*Counsel of Record*)
JUDITH A. STEIN
BRAD S. PLEBANI
WEY-WEY KWOK
CENTER FOR MEDICARE
ADVOCACY, INC.
P.O. Box 350
Willimantic, CT 06226
(860) 456-7790

TOBY S. EDELMAN
CENTER FOR MEDICARE
ADVOCACY, INC.
1025 Connecticut Ave., N.W.,
Suite 709
Washington, DC 20005
(202) 293-5760

Attorneys for Petitioners

May 2009

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2007

(Argued: May 7, 2008 Decided: October 1, 2008
Revised: January 15, 2009)

Docket No. 06-4921-cv

ESTATE OF MARION LANDERS, as represented by its executor, RICHARD LANDERS, MARION A. DIXON, and MURIEL GRIGLEY, on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants-Cross-Appellees,

-v.-

MICHAEL O. LEAVITT, Secretary of the Department of Health and Human Services,

Defendant-Appellee-Cross-Appellant.

Before: HALL and LIVINGSTON, *Circuit Judges.**

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* The Honorable Louis F. Oberdorfer, District Judge, United States District Court for the District of Columbia, who was originally a member of the panel, recused himself after oral argument and had no role in the preparation of this decision. Because the remaining members of the Panel are in agreement, we decide this case in accordance with Second Circuit Interim Local Rule § 0.14(b).

Medicare participants brought this putative class action challenging denial of coverage for post-hospitalization care in skilled nursing facilities. The United States District Court for the District of Connecticut (Janet C. Hall, J.), certified the class, 232 F.R.D. 42, and then granted summary judgment to the defendant, 2006 WL 2560297, holding that the plaintiffs were not entitled to Medicare coverage because the durations of their hospitalization did not meet the statutory qualifying stay requirement. We hold that the interpretation of the qualifying stay requirement set forth in the government's Medicare Benefit Policy Manual is not entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), but we nevertheless find the government's interpretation of the statute persuasive and adopt it.

Affirmed.

GILL DEFORD, Willimantic, Conn. (Judith A. Stein, Brad S. Plebani, Wey-Wey Kwok, Willimantic, Conn., Sally Hart, Tucson, Ariz., Toby Edelman, Washington, D.C., *on the brief*), Center for Medicare Advocacy, *for Plaintiffs-Appellants-Cross-Appellees*.

LEWIS S. YELIN, Attorney, Appellate Staff, Civil Division, U.S. Department of Justice, Washington, D.C. (Scott R. McIntosh, Attorney, Appellate Staff, Peter D. Keisler, Assistant Attorney General, Civil Division, U.S. Department of Justice, Washington, D.C., Kevin J. O'Connor, United States Attorney

for the District of Connecticut, *on the brief*), *for Defendant-Appellee-Cross-Appellant*.

Carol C. Loepere (Elizabeth A. Ransom, *on the brief*), Reed Smith LLP, Washington, D.C., *for Amici Curiae American Health Care Association, Alliance for Quality Nursing Home Care, American Association of Homes and Services for the Aging, National Association of Professional Geriatric Care Managers, Catholic Health Association of the United States, National Association for the Support of Long Term Care, and National Association of Health Care Assistances in Support of Plaintiffs-Appellants-Cross-Appellees*.

Stuart R. Cohen, AARP Foundation Litigation (Bruce Vignery, Stacy Canan, AARP Foundation Litigation, Michael Schuster, AARP, *on the brief*), Washington, DC, *for Amici Curiae AARP, Alliance for Retired Americans, California Advocates for Nursing Home Reform, Greater Boston Legal Services, Long-Term Care Community Coalition, Medicine Rights Center, Michigan Campaign for Quality Care, NCCNHR, and National Senior Citizens Law Center in Support of Plaintiffs-Appellants-Cross-Appellees*.

LIVINGSTON, *Circuit Judge*:

In this case – a dispute about how to count to three – the plaintiffs-appellants are Medicare beneficiaries who appeal from a grant of summary judgment of the United States District Court for the District of Connecticut (Hall, J.). Each of them spent

at least three days in the hospital but was discharged less than three days after having been formally admitted, and each sought coverage under Part A of the Medicare program for a post-hospitalization nursing home stay. After their claims for coverage were initially denied, they brought this lawsuit challenging the denial. The district court granted summary judgment for the government, holding that the plaintiffs were not entitled to Medicare reimbursement because they had not spent the requisite amount of time as hospital inpatients. We agree and therefore affirm.

BACKGROUND

"Medicare is the federal government's health-insurance program for the elderly." *Conn. Dep't of Soc. Servs. v. Leavitt,* 428 F.3d 138, 141 (2d Cir. 2005). It contains four distinct programs, the first of which, known as "Part A," is a hospital insurance program. *See* 42 U.S.C. §§ 1395c to 1395i-5. Part A "provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care" for, among others, eligible people over 65 years of age. *Id.* § 1395c; *see also id.* § 426 (establishing the entitlement to Part A benefits). "Under Part A, service providers such as hospitals are paid the lesser of the 'reasonable cost' of covered services provided to program beneficiaries or 'the customary charges with respect to such services,' and agree not to charge beneficiaries for these services." *Yale-New Haven Hosp. v. Leavitt,* 470 F.3d 71, 73 (2d Cir. 2006)

(citations omitted) (quoting 42 U.S.C. § 1395f(b)(1)); *see also Kraemer v. Heckler*, 737 F.2d 214, 215-16 (2d Cir. 1984) (describing the basic categories of services covered by Part A).

The entitlements under Part A include an extended care benefit, which provides coverage for "post-hospital extended care services for up to 100 days during any spell of illness." 42 U.S.C. § 1395d(a)(2). Part A does not cover all extended care services that follow hospital stays, however. Rather, Part A requires that the hospital stay be a "qualifying" hospital stay before it covers the subsequent extended care. Specifically, the statute defines "post-hospital extended care services" to mean "extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer." *Id.* § 1395x(i). In turn, it defines "extended care services" to mean "services furnished to an inpatient of a skilled nursing facility." *Id.* § 1395x(h). These services include nursing care, bed and board, physical and occupational therapy, and drugs. *Id.* If post-hospital extended care services are not covered by Part A, they still may be covered by Part B. Part B is a voluntary program, however, and unlike Part A beneficiaries, Part B enrollees must pay a monthly premium. *Matthews v. Leavitt*, 452 F.3d 145, 146 n.1 (2d Cir. 2006); *Conn. Dep't of Soc. Servs.*, 428 F.3d at 141 n.2; *Furlong v. Shalala*, 238 F.3d 227, 229 (2d Cir. 2001).

Marion Landers, Marion Dixon, and Muriel Grigley, the first of whom is now deceased and is represented here by her estate, were Medicare beneficiaries who each received inpatient hospital care followed by care at a skilled nursing facility, or "SNF" – essentially, a nursing home. *See* 42 U.S.C. § 1395i-3(a) (defining SNF). Each of them spent three consecutive days in the hospital before moving to the SNF. Yet the Centers for Medicare and Medicaid Services ("CMS") – the federal agency situated within the Department of Health and Human Services ("HHS") that administers the Medicare program on behalf of the Secretary of HHS[1] – denied their claims for coverage with respect to their post-hospitalization SNF stays. CMS did so in accordance with its own rules for determining whether a patient is eligible for post-hospital SNF coverage. According to one such rule, known as the "three-midnight rule," a patient is eligible for SNF coverage only if he or she has been "hospitalized . . . for medically necessary inpatient hospital or inpatient [critical access hospital] care, for

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[1] In 1977, HHS – then called the Department of Health, Education, and Welfare – established the Health Care Financing Administration (the "HCFA"), *see* Reorganization Order, 42 Fed. Reg. 13,262 (Mar. 9, 1977), and vested in it the Secretary's full rulemaking powers under the Medicare statutes, *see* Statement of Organization, Functions, and Delegations of Authority, 49 Fed. Reg. 35,247, 35,248 (Sept. 6, 1984). The HCFA was renamed the Centers for Medicare and Medicaid Services in 2001. *See* Centers for Medicare & Medicaid Services; Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 Fed. Reg. 35,437 (July 5, 2001).

at least 3 consecutive calendar days, not counting the date of discharge." 42 C.F.R. § 409.30(a)(1). And according to another rule, "a patient is considered an inpatient if [he or she is] formally admitted as [an] inpatient." Ctrs. for Medicare & Medicaid Servs., Publ'n No. 100-02, *Medicare Benefit Policy Manual,* ch. 1, § 10 (45th rev. 2006) [hereinafter *Medicare Benefit Policy Manual*], *available at* http://www.cms.hhs.gov/Manuals/IOM/list.asp. Landers, Dixon, and Grigley all spent three – but only three – consecutive midnights in hospitals and then moved to nursing homes, where they received extended care services. But while in the hospital, each of them spent at least one midnight either in the emergency room or on observation status before being formally admitted. Accordingly, CMS determined that, because they had not spent three consecutive midnights hospitalized after having been formally admitted, Part A did not cover their SNF stays.

Landers, Dixon, and Grigley challenged CMS's interpretation of the qualifying hospital stay requirement in a putative class action. They sought a permanent injunction and a writ of mandamus prohibiting the Secretary from excluding Medicare beneficiaries' time in the emergency room and on observation status from counting toward the qualifying stay requirement. The district court granted class certification, *Landers v. Leavitt* (*Landers I*), 232 F.R.D. 42 (D. Conn. 2005), and on cross-motions for summary judgment, ruled in favor of the Secretary, *Landers v. Leavitt* (*Landers II*), No. 3:04-cv-1988

(JCH), 2006 WL 2560297 (D. Conn. Sept. 1, 2006). The plaintiffs now appeal.

DISCUSSION

The plaintiffs challenge the district court's ruling on three grounds. First, they argue that the Medicare statute entitles them to coverage for their post-hospitalization SNF stays. Second, they contend that CMS's interpretation of the statute violates the equal protection guarantee of the U.S. Constitution. Third, they argue that the district court erred by basing its decision exclusively on the administrative record.

I.

The Medicare statute provides coverage for a post-hospitalization SNF stay for a beneficiary who receives extended care services in an SNF after having been "an inpatient for not less than 3 consecutive days" in a hospital. 42 U.S.C. § 1395x(i). Neither the statute nor any applicable regulation defines "inpatient." CMS's policy manual defines an inpatient as a person who has been formally admitted to a hospital. The government urges us to credit the interpretation of the statute that it has set forth in the policy manual. We only consider whether we should defer to the agency's interpretation of the statute, however, upon finding the statute ambiguous. *Gen. Dynamics Land Sys. v. Cline*, 540 U.S. 581, 600 (2004) ("[D]eference to [an agency's] statutory interpretation is called for only when the devices

of judicial construction have been tried and found to yield no clear sense of congressional intent." (citing *INS v. Cardoza-Fonseca,* 480 U.S. 421, 446 (1987))); *Kruse v. Wells Fargo Home Mortg., Inc.,* 383 F.3d 49, 55 (2d Cir. 2004) ("If the provisions of the statute are unclear or ambiguous . . . we must decide whether to defer to [the agency's] reading of them. . . . If we decide that we are to defer, we must then decide the appropriate level of deference."). We have little difficulty finding ambiguity here. The statute provides no definition of "inpatient," and both the plaintiffs and the agency can cite to dictionary definitions supporting their competing definitions. *See* Webster's Third New International Dictionary 1167 (1976) (defining "inpatient" as "a patient in a hospital or infirmary who receives lodging and food as well as treatment"); American Heritage Dictionary of the English Language 932 (3d ed. 1992) (defining "inpatient" as "[a] patient who is admitted to a hospital or clinic for treatment that requires at least one overnight stay"); *see also* Oxford English Dictionary (2d ed. 1989) (defining "inpatient" as "a patient who remains in a hospital while under medical treatment"). Therefore, we agree with the agency that the statute is ambiguous as to whether pre-admission time spent in observation and in the emergency room should be considered "inpatient" time upon the patient's later admission.

The next question for us is whether the agency's interpretation of "inpatient" is of the type that is eligible for deference under *Chevron U.S.A. Inc. v.*

Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). If it is, then we proceed with a *Chevron* analysis. *McNamee v. Dep't of the Treasury*, 488 F.3d 100, 105 (2d Cir. 2007); *Levine v. Apker*, 455 F.3d 71, 80 (2d Cir. 2006). If not, then we construe the statute in the first instance, giving effect to CMS's nonlegislative interpretation to the extent we find it persuasive in accordance with *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). We review de novo these questions of law that the district court addressed on cross-motions for summary judgment. *Krauss v. Oxford Health Plans, Inc.*, 517 F.3d 614, 621-22 (2d Cir. 2008); *Prot. & Advocacy for Persons with Disabilities v. Mental Health & Addiction Servs.*, 448 F.3d 119, 123 (2d Cir. 2006); *Butts v. Barnhart*, 388 F.3d 377, 384 (2d Cir. 2004), *amended on reh'g in part*,416 F.3d 101 (2d Cir. 2005).

A.

"[A]n 'administrative implementation of a . . . statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" *Rotimi v. Gonzales*, 473 F.3d 55, 57 (2d Cir. 2007) (per curiam) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001)). The first half of this test is clearly satisfied: Congress has delegated general rulemaking authority with respect to Medicare to the Secretary of HHS, who in turn has

delegated that authority to CMS. *See, e.g.*,42 U.S.C. § 1395ff(a)(1) ("The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A or part B of this subchapter in accordance with those regulations. . . . "); *id.* § 1395hh(a)(1) ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter."); *see also Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995) (recognizing "the Medicare statute's broad delegation of authority"); *New York ex rel. Stein v. Sec'y of Health & Human Servs.*, 924 F.2d 431, 433 (2d Cir. 1991) ("Resolution of Medicare reimbursement issues requires an understanding of complicated and technical facts, and Congress has delegated these difficult decisions to the agency that has specialized knowledge in the area."). Thus, we move to the second half of the test and consider whether CMS has promulgated its interpretation in the exercise of its authority.

Most agency interpretations that have qualified for *Chevron* deference are rules that have been promulgated in "regulations issued through notice and comment or adjudication, or in another format authorized by Congress for use in issuing 'legislative' rules." *Cmty. Health Ctr. v. Wilson-Coker,* 311 F.3d 132, 138 (2d Cir. 2002) (citations omitted); *see also Mead,* 533 U.S. at 230 ("[T]he overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication."). The policy manual provision

at issue here, of course, is not the product of notice-and-comment rulemaking or formal adjudication. Nevertheless, less formal, nonlegislative interpretations are not for that reason alone disqualified from receiving *Chevron* deference. *See Barnhart v. Walton*, 535 U.S. 212, 221-22 (2002); *Mead*, 533 U.S. at 230-31; *Cmty. Health Ctr.*, 311 F.3d at 138; *see also Gonzales v. Oregon*, 546 U.S. 243, 258-69 (2006) (considering at great length whether an interpretive rule was eligible for *Chevron* deference but ultimately answering in the negative).

Although nonlegislative rules are not per se ineligible for *Chevron* deference as a general matter, we are aware of few, if any, instances in which an agency manual, in particular, has been accorded *Chevron* deference.[2] Indeed, we have remarked that

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[2] Arguing to the contrary, the government points us to the Ninth Circuit's recent decision in *County of Los Angeles v. Leavitt*, 521 F.3d 1073 (9th Cir. 2008), which cited *Chevron* in discussing a definition set forth in CMS's Medicare Provider Reimbursement Manual. *Id.* at 1078. The Ninth Circuit has clearly stated, however, that Medicare policy manuals are interpretive rules and therefore do not receive *Chevron* deference. *See Erringer v. Thompson*, 371 F.3d 625, 629-33 (9th Cir. 2004); *Cmty. Hosp. v. Thompson*, 323 F.3d 782, 788, 791 (9th Cir. 2003); *see also Omohundro v. United States*, 300 F.3d 1065, 1068 (9th Cir. 2002) (per curiam) ("[A]n administrative agency's interpretation of a statute contained in an informal rulemaking must be accorded the level of deference set forth in *Skidmore*. . . . "). Moreover, although the court in *Los Angeles* cited *Chevron*, it appeared elsewhere in the opinion to treat the manual provision as an interpretive rule to be considered in

(Continued on following page)

Christensen v. Harris County, 529 U.S. 576 (2000), "made clear that 'interpretations contained in policy statements, agency manuals and enforcement guidelines . . . do not warrant *Chevron* style deference.'" *De La Mota v. U.S. Dep't of Educ.,* 412 F.3d 71, 79 (2d Cir. 2005) (quoting *Christensen,* 529 U.S. at 587). Although both *Barnhart* and *Mead* recognized that some subset of informal interpretations can receive *Chevron* deference, the sole example that both cases cite, *NationsBank v. Variable Annuity Life Insurance Co.,* 513 U.S. 251 (1995), concerned an agency opinion letter, *id.* at 255, which is qualitatively different from an agency manual. Neither *Barnhart* nor *Mead* casts doubt on prior pronouncements that agency manuals, as a class, are generally ineligible for *Chevron* deference. *See Mead,* 533 U.S. at 234 (describing policy statements, agency manuals, and enforcement guidelines as "beyond the *Chevron* pale"); *Guernsey Mem'l Hosp.,* 514 U.S. at 99 (definition in HHS's Medicare Provider Reimbursement Manual "is a prototypical example of an interpretive rule" and therefore "do[es] not have the force and effect of law and [is] not accorded that weight in the adjudicatory process"); *Pub. Citizen, Inc. v. U.S. Dep't of Health & Human Servs.,* 332 F.3d 654, 660 (D.C. Cir. 2003) (*Mead* and *Christensen* "cited 'agency manuals' as an archetype of the kind of document that is not entitled to *[Chevron]* deference"). We therefore decline to accord *Chevron*

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accordance with *Skidmore. Los Angeles,* 521 F.3d at 1077 n.5; *id.* at 1079 n.8.

deference to the interpretation of "inpatient" in CMS's policy manual.

B.

An agency interpretation that does not qualify for *Chevron* deference is still entitled to "respect according to its persuasiveness," *Mead,* 533 U.S. at 221, as evidenced by "the thoroughness evident in [the agency's] consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade," *id.* at 228 (quoting *Skidmore,* 323 U.S. at 140). As we conduct this inquiry, we are mindful of the Supreme Court's repeated suggestion that HHS interpretations, in particular, should receive more respect than the mine-run of agency interpretations. *See, e.g., Thomas Jefferson Univ. v. Shalala,* 512 U.S. 504, 512 (1994); *Schweiker v. Gray Panthers,* 453 U.S. 34, 43 & n.14 (1981). Indeed, we have observed that, in cases such as those involving Medicare or Medicaid, in which CMS, "a highly expert agency[,] administers a large complex regulatory scheme in cooperation with many other institutional actors, the various possible standards for deference" – namely, *Chevron* and *Skidmore* – "begin to converge." *Cmty. Health Ctr.,* 311 F.3d at 138.

1.

Our analysis of the *Skidmore* factors in this case leads us to conclude that CMS's interpretation is

entitled to a great deal of persuasive weight. First, CMS's interpretation is longstanding. *See N. Haven Bd. of Educ. v. Bell,* 456 U.S. 512, 522 n.12 (1982) ("In construing a statute, this Court normally accords great deference to the interpretation, particularly when it is longstanding, of the agency charged with the statute's administration."). Medicare came into existence in 1965. *See* Health Insurance for the Aged Act, Pub. L. No. 89-97, tit. I, 79 Stat. 290 (1965). A nearly contemporaneous HHS regulation established a rule that, like CMS's current rule, began counting inpatient days for purposes of the qualifying stay requirement on the day the patient was formally admitted:

> *The 3 consecutive days as a hospital inpatient; defined.* The 3-consecutive-day hospital inpatient requirement is a period of 3 consecutive calendar days beginning with the calendar day of admission even if less than a 24-hour day, and ending with the day before the calendar day of discharge. Thus, in determining whether the 3-consecutive-day requirement is met, the day of admission is counted as one day; the day of discharge is not counted as a day; and each intervening day is counted as a single day.

20 C.F.R. § 405.120(c) (1966).[3] CMS's interpretation thus reflects a position that HHS first adopted more than 40 years ago.

Second, CMS is consistent in its interpretation, employing the same definition elsewhere in its guidance manual and expressly declining to count time on observation status or in the emergency room toward the qualifying stay requirement. *See Medicare Benefit Policy Manual, supra,* ch. 8, § 20.1. This section of the policy manual also references the 1966 Federal Register publication in which HHS promulgated § 405.120(c), which further bolsters the conclusion that CMS desires to maintain its consistent and long-held position.

The plaintiffs urge us to find the government's position inconsistent based on the way in which CMS reimburses beneficiaries for their hospital stays. The plaintiffs in this case sought Medicare reimbursement not only for their post-hospitalization SNF stays, but also for the time they spent in hospitals

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[3] This regulation, although codified, was not subject to the Administrative Procedure Act's notice-and-comment process because Medicare regulations were not subject to 5 U.S.C. § 553(b)'s requirements until 1971. *Nat'l Med. Enters., Inc. v. Sullivan,* 957 F.2d 664, 670 n.8 (9th Cir. 1992); *see also* Public Participation in Rule Making, 36 Fed. Reg. 2532 (Feb. 5, 1971) (statement of the Secretary of Health, Education, and Welfare opting into the procedures specified by § 553). Even though not adopted pursuant to relatively formal procedures, however, the regulation still evidences the longstanding nature of the agency's view.

before their SNF stays. The same section of the Medicare statute that provides coverage for post-hospitalization SNF stays also provides coverage for hospital stays, in the latter case for "inpatient hospital services . . . for up to 150 days during any spell of illness." 42 U.S.C. § 1395d(a)(1). Yet the plaintiffs were reimbursed *both* for the services they received after they were formally admitted – in the government's view, the only time during which they were inpatients – *and* for the services they received while in the emergency room and on observation status before being formally admitted. This reimbursement policy, the plaintiffs contend, makes the government's position with respect to SNF reimbursement unreasonable and inconsistent: if pre-admission emergency room and observation status services are "inpatient hospital services," why should time spent in the emergency room or on observation status not count as "inpatient" hospital time for the purpose of meeting the qualifying stay requirement?

The difficulty with this argument is that the statute mandates – or at least strongly counsels in favor of making – precisely the distinction that the government has drawn. Part A's reimbursements for inpatient hospital services are determined by reference to the statutory term "operating costs of inpatient hospital services." As the statute defines that term, it means operating costs "with respect to inpatient hospital services . . . , *and includes the costs of all services* for which payment may be made under this subchapter that are provided by the hospital . . . *to the*

patient during the 3 days . . . immediately preceding the date of the patient's admission if such services are . . . related to the admission." 42 U.S.C. § 1395ww(a)(4) (emphases added). Thus, § 1395ww(a)(4) directs CMS to provide coverage for an inpatient hospital stay and up to three days of related in-hospital services rendered before the patient was admitted to the hospital. The statute does not, however, require or even suggest that the pre-admission days themselves be treated as inpatient days. Indeed, CMS has relied on this aspect of the statute to explain its present position. *See* Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, 70 Fed. Reg. 29,070, 29,100 (May 19, 2005) [hereinafter 2005 Proposed Rules]. Accordingly, regardless of whether we think it sensible as a policy matter for CMS to reimburse pre-admission hospital services as if they were inpatient services but not consider that time to be part of a pre-SNF inpatient stay, the *statutory* requirement that pre-admission services be reimbursed leads us to find no *regulatory* inconsistency in CMS's decision not to count pre-admission hospital time in determining whether a patient has had an SNF qualifying stay.

Third, CMS has recently reconsidered its position on the public record. In 2005, CMS "invite[d] comments on whether [it] should consider the possibility of counting the time spent in observation status toward meeting the SNF benefit's qualifying 3-day hospital stay requirement." *Id.* at 29,099. In inviting these comments, CMS observed that the three-day

stay requirement was designed "to target the SNF benefit more effectively at the limited segment of the nursing home population that the benefit was actually designed to cover (that is, those beneficiaries requiring a short-term, fairly intensive stay in a SNF as a continuation of an acute hospital stay of several days)." *Id.* It observed, further, that the medical practice of placing patients on observation status before formally admitting them has grown in prevalence since Congress enacted the Medicare statute in 1965, that some commentators have suggested that patients on observation status receive qualitatively the same type of care as admitted patients, and that some view it as unfair for Medicare reimbursement decisions to turn on a distinction that they believe to be "a mere recordkeeping convention on the part of the hospital rather than a substantive change in the actual care that the beneficiary receives there." *Id.*

Following this invitation, CMS received comments on this precise issue. Many of these comments "expressed support for the idea that hospital time spent in observation status immediately preceding a formal inpatient admission should count toward satisfying the SNF benefit's statutory qualifying three-day hospital stay requirement." Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, 70 Fed. Reg. 45,026, 45,050 (Aug. 4, 2005). "[S]ome others supported counting the observation time," but not "time spent in the emergency room." *Id.*

Ultimately, however, CMS declined to change its interpretation. With regard to the suggestion that emergency room time count toward the qualifying stay requirement, CMS "d[id] not share the belief . . . that time spent in the emergency room is essentially comparable to observation time in this context" because "the mere presence of time spent in the emergency room prior to formal admission would not, in itself, serve to identify the degree of severity of a particular patient's condition during that time." *Id.* With regard to the suggestion that time on observation status count toward the requirement, CMS stated that it was "continuing to review this issue, but [was] not yet ready to make a final determination." *Id.* CMS was wary of changing its interpretation, it said, because it did not want to adopt a reimbursement guideline that conflicted with what it viewed as Congress's "intent in establishing the qualifying hospital stay requirement" – namely, that the SNF benefit "serv[e] as a less expensive alternative to what would otherwise be the final, convalescent portion of an acute care stay of several days as an inpatient at a hospital." *Id.* at 45,051.

The preceding exchange shows that CMS opened its policies to public comment, received comments challenging the interpretation at issue in this case, and declined to change its position in light of what it perceives as Congress's intent in imposing the qualifying stay requirement. CMS's statement with respect to observation status may be less than wholly satisfying, but it is not so deficient that it lacks

persuasive force. To be sure, we may reject an agency interpretation that merely "mirrors the common understanding" at the time the agency adopted its interpretation but has not been revised to reflect "changing circumstances, particularly in areas characterized by rapid technological development." *Detsel v. Sullivan,* 895 F.2d 58, 63-64 (2d Cir. 1990). Here, however, CMS does not attempt to justify its position by arguing that it was reasonable when first adopted. Rather, CMS appears to be acutely aware of the changes in medical practice since the 1960s and has declined to include time on observation status toward the three-day count because, in its view, doing so would risk undermining congressional intent. We are thus unable to conclude that CMS "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence" before it. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

The plaintiffs urge us to view this public comment opportunity and CMS's reconsideration of its interpretation as a farce or as otherwise tainted because it was conducted during the pendency of this litigation. We decline to do so. Although we do not defer to agency constructions of statutes asserted as litigating positions, *see Rhodes-Bradford v. Keisler,* 507 F.3d 77, 80 (2d Cir. 2007) (citing *Bowen v. Georgetown Univ. Hosp.,* 488 U.S. 204, 212-13 (1988)), CMS presented its construction to the public at large and considered its position as a generally applicable

matter rather than for a single litigation. The law generally seeks to encourage public participation in agency decisionmaking, *see Am. Postal Workers Union v. U.S. Postal Serv.*, 707 F.2d 548, 565 (D.C. Cir. 1983); *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978), and we would frustrate rather than further that goal if we were to strip an agency of deference it would otherwise be due merely because that public participation was spurred by litigation rather than arising from the agency's self-generated desire or beneficence. By way of analogy, a duly promulgated agency regulation enjoys the full extent of *Chevron* deference even when the regulation was prompted by pending litigation that lurked in the background. *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 740-41 (1996). The plaintiffs proffer no persuasive reason why we should question the integrity of CMS's deliberative process here given that we would decline to do so in the *Chevron* context.

Fourth, CMS's rule is the product of an interpretation that is relatively formal within the universe of informal interpretations. "[T]he deference due" to an agency interpretation "is at the high end of the spectrum of deference" when "the interpretation in question is not merely ad hoc but . . . is applicable to all cases." *Chauffer's Training Sch., Inc. v. Spellings*, 478 F.3d 117, 129 (2d Cir. 2007). CMS's interpretation, set forth in a policy manual rather than, for example, a nonprecedential letter ruling, is generally applicable and is not an ad hoc position. In the Medicaid context,

we have regarded a CMS manual as meriting an "intermediate level" of deference that lies "between a published recommendation and an interpretation advanced only in litigation," *Rabin v. Wilson-Coker*, 362 F.3d 190, 198 (2d Cir. 2004), and we do the same here.

* * *

In sum, the *Skidmore* factors lead us to regard the statutory interpretation set forth in CMS's policy manual as persuasive.

2.

In view of our *Skidmore* analysis, we conclude that a Medicare beneficiary is not an inpatient within the meaning of § 1395x(i) unless he or she has been formally admitted to a hospital. We reach this conclusion not only because our decision is informed by CMS's highly persuasive interpretation, but also because it accords with the statutory text and our governing precedents.

The statutory definition of inpatient hospital services enumerates such services as "bed and board," 42 U.S.C. § 1395x(b)(1), "nursing services," *id.* § 1395x(b)(2), and "other diagnostic or therapeutic items or services," *id.* § 1395x(b)(3). The plaintiffs urge us to credit their argument that anyone who receives these services in the hospital is receiving inpatient hospital services and is therefore an inpatient. In light of the statutory text, however, this

argument is ultimately question-begging. The statute defines inpatient hospital services to include the aforementioned items and services when they are "furnished *to an inpatient of a hospital* and . . . by the hospital." *Id.* § 1395x(b) (emphasis added). Thus, services cannot be inpatient hospital services unless they are furnished to an inpatient. The construction of the statute that the plaintiffs propose would read the words "to an inpatient of a hospital" out of the statutory text. The facts of this case demonstrate, at most, that the services rendered to the plaintiffs *would* have been inpatient hospital services *if* the plaintiffs had been inpatients. Unfortunately, that is not enough to entitle the plaintiffs to reimbursement because it still leaves unanswered the essential issue of defining an inpatient.

The conclusion here – that one is an inpatient for the purpose of § 1395x(i) only if one has been formally admitted to a hospital – is also not in tension with our decision in *Levi v. Heckler,* 736 F.2d 848 (2d Cir. 1984) (per curiam), or those of the other Courts of Appeals that have adopted the same reasoning, *see Mayburg v. Sec'y of Health & Human Servs.,* 740 F.2d 100 (1st Cir. 1984) (Breyer, J.); *Kaufman v. Harris,* 731 F.2d 370 (6th Cir. 1984) (per curiam); *Friedberg v. Schweiker,* 721 F.2d 445 (3d Cir. 1983) (per curiam). These cases concerned Medicare's coverage of inpatient hospital services, for which Medicare participants are entitled to reimbursement "for up to 150 days during any spell of illness." 42 U.S.C. § 1395d(a)(1). Under the statute, a spell of illness

begins on the first day a patient is furnished inpatient hospital services and ends when he or she is neither an inpatient of a hospital nor an inpatient of an SNF. *Id.* § 1395x(a). In *Levi,* we defined an inpatient of an SNF to mean a patient "who both resides in a skilled nursing facility *and* receives the 'skilled nursing care' there available," 736 F.2d at 849 (quoting *Levi v. Heckler,* 575 F. Supp. 1381, 1384 (S.D.N.Y. 1983)) (internal quotation mark omitted), and thus held that a patient's spell of illness ended if he resided in an SNF but received only custodial care, not nursing care. But in *Levi,* we considered only whether formal residence in an SNF was *sufficient* to render one an inpatient of that facility. We had no occasion to address the analogue of the question that is presented here: whether formal admission or formal residence is *necessary* to render one an inpatient. *Levi* therefore does not shed light on the question at issue.

Accordingly, we conclude this portion of our opinion by reiterating our core holding in this case: in determining whether a Medicare beneficiary has met the statutory three-day hospital stay requirement needed to qualify for post-hospitalization SNF benefits under Part A, the time that the patient spends in the emergency room or on observation status before being formally admitted to the hospital does not count. In so holding, we expressly reject the rule of *Jenkel v. Shalala,* 845 F. Supp. 69 (D. Conn. 1994), which held that "later 'formal admission'" of a patient following her treatment in the emergency room operates as "a nunc pro tunc ratification of her de

facto admission at the time of her arrival in the emergency room." *Id.* at 71 (emphasis omitted). As a postscript to this portion of our holding, we note that the Medicare statute does not unambiguously require the construction we have adopted. If CMS were to promulgate a different definition of inpatient in the exercise of its authority to make rules carrying the force of law, that definition would be eligible for *Chevron* deference notwithstanding our holding today. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-86 (2005).

II.

The plaintiffs also challenge the constitutionality of CMS's rule, arguing that it violates their rights to equal protection under the Fifth Amendment. *See Nicholas v. Tucker*, 114 F.3d 17, 19 (2d Cir. 1997) ("Although . . . the Fifth [Amendment] does not contain an equal protection clause, 'it does forbid discrimination that is "so unjustifiable as to be violative of due process."' The standards for analyzing equal protection claims under either [the Fifth or the Fourteenth A]mendment are identical." (citation omitted) (quoting *Schneider v. Rusk*, 377 U.S. 163, 168 (1964))). Specifically, they contend that the rule unlawfully discriminates against Medicare patients who spend time in the emergency room or on observation status by treating them less favorably than those who are formally admitted immediately upon arriving or very soon thereafter.

The plaintiffs concede that CMS's interpretation does not implicate any suspect classifications and that, therefore, we should apply rational basis scrutiny. *See Furlong v. Shalala,* 156 F.3d 384, 392 (2d Cir. 1998). Accordingly, we should find the interpretation constitutionally valid if it is "rationally related to a legitimate government interest," *Kraham v. Lippman,* 478 F.3d 502, 506 (2d Cir. 2007), and strike it down as unconstitutional only if the plaintiffs "demonstrate that the government regulation is arbitrary and/or unreasonable, and not rationally related to a legitimate government interest," *Tanov v. INS,* 443 F.3d 195, 201 (2d Cir. 2006).

We conclude that the rule does not violate the Constitution's guarantee of equal protection. As CMS has noted, Congress intended to create an extended care benefit to serve "as a less expensive alternative to . . . the final, convalescent portion of an acute care stay . . . at a hospital." Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2006, 70 Fed. Reg. 29,070, 29,099 (May 19, 2005). CMS rationally could have concluded that a bright line rule measuring inpatient time based on formal admission would simplify claims processing and reduce administration costs, while targeting the program at the group Congress intended to benefit. CMS's legitimate interest in administrative efficiency is sufficient to uphold this rule against a rational basis challenge. *See Ellis v. Apfel,* 147 F.3d 139, 146 (2d Cir. 1998).

III.

Plaintiff's final argument is that the district court erred when it refused to consider evidence outside the administrative record. Judicial review of administrative determinations with respect to Medicare benefits is governed by 42 U.S.C. § 1395ff(b)(1)(A), which incorporates the provisions of 42 U.S.C. § 405(g). According to the latter statute, the district court ordinarily must base its judgment "upon the pleadings and transcript of the record." 42 U.S.C. § 405(g); *see also Mathews v. Weber*, 423 U.S. 261, 263 (1976) (noting that, under § 405(g), "[t]he court may consider only the pleadings and administrative record, and must accept the Secretary's findings of fact so long as they are supported by substantial evidence"); *id.* at 270 ("[Under § 405(g),] neither party may put any additional evidence before the district court."). Nevertheless, the district court has "adequate authority to resolve any statutory or constitutional contention that the agency [did] not, or cannot, decide," a power that includes, "where necessary, the authority to develop an evidentiary record." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 23-24 (2000).

In support of their motion for summary judgment, the plaintiffs submitted a statement of material facts, several declarations, and interrogatories in which CMS officials explained the policy at issue. The district court granted the government's motion to strike these extra-record submissions, ruling that because the case presents "a purely legal challenge to the Secretary's policy," it "does not require factual

determinations with respect to individual plaintiffs that would require resort to evidence outside the administrative record." *Landers II,* 2006 WL 2560297, at *3. Because the district court's decision not to admit evidence outside the record is an exercise of its "authority to develop an evidentiary record," *Ill. Council on Long Term Care,* 529 U.S. at 23-24, we review that decision for abuse of discretion. *Arlio v. Lively,* 474 F.3d 46, 51 (2d Cir. 2007) ("We review evidentiary rulings for abuse of discretion." (citing *Caruolo v. John Crane, Inc.,* 226 F.3d 46, 54 (2d Cir. 2000))).

The district court correctly excluded the interrogatories. In the ordinary case, we must uphold or set aside the agency's action on the grounds that the agency has articulated. *State Farm,* 463 U.S. at 50. Supplementation of the administrative record may be appropriate if "there was such failure to explain administrative action as to frustrate effective judicial review," *Camp v. Pitts,* 411 U.S. 138, 142-43 (1973) (per curiam), but we find no such failure here. As discussed above, we find the agency's justification of its decision not to change its interpretation "discloseſs] the factors that were considered," *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971), and adequately explains its action. *See Camp*, 411 U.S. at 142. The plaintiffs argue that this principle of judicial review creates a risk that agencies will be able to hoodwink courts into accepting agencies' self-interested justifications, but we are unwilling to ascribe such nefarious motives to agency

action as a general matter. *See U.S. Postal Serv. v. Gregory,* 534 U.S. 1, 10 (2001) ("[A] presumption of regularity attaches to the actions of Government agencies. . . ."); *Withrow v. Larkin,* 421 U.S. 35, 47 (1975) (referring to the "presumption of honesty and integrity in those serving as [agency] adjudicators"). It is well-established that courts should focus exclusively on the formal administrative record unless that record is insufficient to shed light on the rationale for the agency's decision. The record here is sufficient and we decline to consider additional evidence.

The district court also correctly excluded the plaintiffs' declarations and statement of material facts. The facts set forth in these submissions are not material to the plaintiffs' eligibility for reimbursement because the nature of the medical services rendered to the plaintiffs cannot, by themselves, establish the plaintiffs' eligibility for SNF coverage. *See Jones v. Sullivan,* 949 F.2d 57, 60 (2d Cir. 1991) ("The concept of materiality requires . . . a reasonable possibility that the new evidence would have influenced the Secretary to decide [the] claimant's application differently."). In refusing to consider these submissions, therefore, the district court acted within its sound discretion.

CONCLUSION

For the foregoing reasons, we affirm the judgment of the district court.

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

MARION LANDERS, MARION DIXON, and MURIEL GRIGLEY, on behalf of themselves and all others similarly situated,	:	CIVIL ACTION NO. 3:04-cv-1988 (JCH)
Plaintiffs,	:	
v.	:	SEPTEMBER 1, 2006
MICHAEL O. LEAVITT, Secretary of the Department of Health and Human Services,	:	
Defendant.	:	

RULING ON CROSS MOTIONS FOR SUMMARY JUDGMENT [Doc. Nos. 55 & 59] AND DEFENDANT'S MOTION TO STRIKE PLAINTIFF'S STATEMENT OF MATERIAL FACTS [Doc. No. 72]

I. INTRODUCTION

The named plaintiffs were Medicare beneficiaries who were denied coverage for stays in skilled nursing facilities ("SNFs").[1] Medicare, Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides coverage

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[1] One of the lead plaintiffs, Marion Landers, recently passed away, and her Estate has been substituted as a party plaintiff.

for such stays. However, it does so only where services are "furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer." 42 U.S.C. § 1395x(i). The named plaintiffs were initially denied coverage on the basis that they had not spent three or more days as hospital "inpatients" prior to transfer to the SNFs.

The plaintiffs challenge the interpretation of the three-day qualifying stay requirement that has been advanced and applied by the Secretary of the Department of Health and Human Services ("Secretary"). The plaintiffs claim that the Secretary failed to include time spent in the emergency room, or on observation status, in his calculation of the time spent in a hospital, contrary to applicable statutes, regulations, and the Equal Protection clause of the United States Constitution.

This court has certified a class pursuant to Rules 23(a) and (b)(2) of the Federal Rules of Civil Procedure, with named plaintiffs Marion Landers, Marion A. Dixon, and Muriel Grigley as the class representatives and the class defined as follows:

> All Medicare beneficiaries who (1) have been or will be in a hospital for at least three consecutive days prior to discharge from the hospital; (2) were or will be in the emergency room and/or in observation status for some portion of those days in the hospital; (3) were or will be admitted formally as an inpatient

> for at least one of those days; (4) after a claim has been or will be filed on their behalf, have been or will be denied Medicare coverage for skilled nursing facility care because of spending less than three days as a formally admitted inpatient; and (5) have or will have a claim pending for the Medicare coverage so denied at some level of the administrative process, or have filed or could timely file for review at either the next level of the administrative process or in federal district court, within sixty (60) days prior to the date of the filing of this complaint.

Landers v. Leavitt, 232 F.R.D. 42, 48-49 (D.Conn. 2005).

Both the plaintiffs and the Secretary have moved for summary judgment.[2] The Secretary also moves to strike the plaintiffs' Local Rule 56(a)1 Statement of Facts and the declarations the plaintiffs submitted in support of their motion for summary judgment. *See* Def.'s Mot to Strike [Doc. No. 72].

II. STANDARD OF REVIEW

In a motion for summary judgment, the burden lies on the moving party to establish that there are no genuine issues of material fact in dispute and that it

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[2] The American Health Care Association and the American Medical Directors Association have also filed an *amicus curiae* brief urging the court to rule in favor of the plaintiffs. [Doc. No. 71].

is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986); *SCS Communications, Inc. v. Herrick Co.*, 360 F.3d 329, 338 (2d Cir. 2004). The moving party may satisfy this burden "by showing – that is pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (per curiam) (internal quotation marks and citations omitted); *accord Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995). The parties in the present action agree that summary judgment is appropriate, but dispute the legal conclusion that the court should reach.

III. FACTS

The facts surrounding the hospitalizations of the named plaintiffs are summarized in this court's ruling on the motion for class certification. 232 F.R.D. at 44-45. The three lead plaintiffs in this case all received treatment from hospitals for at least three days before being transferred to skilled nursing facilities ("SNFs"). All spent some of this time in the emergency room or on "observation" status, before being formally admitted to the hospital as inpatients. All spent less than three days in formal inpatient status. The Center for Medicare & Medicaid Services ("CMS") initially denied coverage to all of the lead

defendants [plaintiffs] for the SNF stays that followed their hospitalizations.[3]

IV. DISCUSSION

A. Motion to Strike

The Secretary has moved to strike the plaintiffs' Local Rule 56(a)1 statement of facts and the declarations that the plaintiffs submitted in support of their motion for summary judgment. [Doc. No. 72]. He argues that the scope of the court's review of administrative action is limited to the administrative record.

In order to resolve this motion, the court must first articulate the basis for its jurisdiction. The plaintiffs assert in their Complaint that this court has jurisdiction pursuant to the federal question statute, 28 U.S.C. § 1331, the mandamus statute, *id.* at § 1361, and the applicable judicial review provisions in the Social Security Act, 42 U.S.C. § 1395ff(b)[4]

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[3] Two of the lead plaintiffs, Marion Dixon ("Dixon") and Muriel Grigley ("Grigley"), eventually obtained favorable decisions from administrative law judges ("ALJs") with respect to their claims for SNF coverage. However, this court has previously held that those favorable decisions did not moot their claims for purposes of this class action. 232 F.R.D. at 46-47.

[4] This section permits judicial review of Medicare determinations:

> Reconsideration of Initial Determination. Subject to subparagraph (D) [time limits], any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and

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& 405(g).[5] However, mandamus relief is not available in this action because the plaintiffs have an alternate

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(E) [amount in controversy requirement], a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to paragraph (2) [expedited access to judicial review], to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

42 U.S.C. § 1395ff(b)(1)(A).

[5] This section reads,

Judicial review. Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the District Court of the United States for the District of Columbia [United States District Court for the District of Columbia]. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive,

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and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) hereof which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) hereof, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and, in any case in which the Commissioner has not made a decision fully favorable to the individual, a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person

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and adequate avenue for relief in the judicial review provided by the Social Security Act and the Medicare Act. *See Aref v. United States,* 452 F.3d 202, 206 (2d Cir. 2006) (internal citation and quotation marks omitted) ("Mandamus is an extraordinary remedy, available only in extraordinary circumstances, and will be granted only if petitioner shows (1) the presence of a novel and significant question of law; (2) the inadequacy of other available remedies; and (3) the presence of a legal issue whose resolution will aid in the administration of justice."). Although section 405(h) does not bar mandamus relief "under circumstances where the writ properly would issue," *City of New York v. Heckler,* 742 F.2d 729, 739 (2d Cir. 1984), the present case does not present an appropriate circumstance for mandamus jurisdiction. The parties do not appear to dispute that section 405(g) applies to all class members, and so the court does not find it necessary to make use of the mandamus statute as an alternate source of jurisdiction. *Cf. Heckler,* 742 F.3d at 739.

Additionally, as this court recognized in its ruling on class certification, "Section 405(h) precludes federal-question jurisdiction in an action challenging denial of claimed benefits. The only avenue for judicial relief is 42 U.S.C. § 405(g). . . ." *Landers v. Leavitt,* 232 F.R.D. 42, 45 (D.Conn. 2005) (quoting *Mathews v.*

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occupying the office of Commissioner of Social Security or any vacancy in such office.

42 U.S.C. § 405(g).

Eldrige [sic], 424 U.S. 319, 327 (1976)); *see Shalala v. Ill. Council on Long Term Care,* 529 U.S. 1, 10 (2000) (holding that § 405(h) "plainly bars § 1331 review" in cases in which an individual who has been denied a Medicare or Social Security benefit challenges the lawfulness of such denial, "irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds."). Therefore, the jurisdiction for this case lies under the Social Security Act and Medicare Act judicial review provisions only.

Because this case is proceeding under the judicial review provisions of the Social Security Act, incorporated by reference in the Medicare Act, the court's review of facts is limited to the administrative record. *See Mathews v. Weber,* 423 U.S. 261, 263, 270 (1976) (holding that, under 42 U.S.C. § 405(g), the "court may consider only the pleadings and administrative record" and "neither party may put any additional evidence before the district court"). The plaintiffs' arguments do not persuade the court otherwise. The cases cited by the plaintiffs, *Bowen v. City of New York,* 476 U.S. 467, 484-85 (1986), *State of New York v. Sullivan,* 906 F.2d 910, 918 (2d Cir. 1990), and *City of New York v. Heckler,* 742 F.2d 729, 736-37 (2d Cir. 1983), *aff'd,* 476 U.S. 467 (1986), all dealt with waiver of the administrative exhaustion requirement, and not whether courts could consider materials outside the administrative record. Neither *Bowen,* nor *Sullivan,* nor *Heckler* suggest that, where exhaustion is waived, the court should consider facts

outside the administrative record. Indeed, the instant challenge is presented as a purely legal challenge to the Secretary's policy, and does not require factual determinations with respect to individual plaintiffs that would require resort to evidence outside the administrative record. *See* Plfs.' Mem. Opp. Def.'s Mot. to Strike at 3 [Doc. No. 74] ("The instant case . . . cannot be resolved based on the administrative record because the individual plaintiff's record below has little bearing on the policy challenge, except to demonstrate how the policy is applied in a typical scenario.").

Although the Third Circuit has held that, "Section 405(g) permits consideration of additional evidence on a showing of 'good cause for the failure to incorporate such evidence into the [agency] record,'" *Hummel v. Heckler,* 736 F.2d 91, 95 (3d Cir. 1984) (quoting 42 U.S.C. § 405(g)), *cited in* Plf.'s Mem. Opp. Def.'s Mot. to Strike at 3 [Doc. No. 74], *Hummel,* unlike the present case, involved a challenge to the fairness of administrative proceedings. Moreover, the instant plaintiffs have not shown good cause. Finally, the plaintiffs' citation to *Hill v. Sullivan,* 125 F.R.D. 86, 87-88 (S.D.N.Y.1989), does not support their position because *Hill* did not rule on the admissibility of evidence outside the administrative record.

The plaintiffs argue further that this court's denial of the Secretary's motion for a protective order to avoid discovery [Doc. No. 40] necessarily implies that this court found that facts outside the administrative record were admissible. However, that order,

issued without written opinion, did not make a finding as to the ultimate admissibility of the discovery materials that the plaintiffs sought, nor whether the administrative record before the court was complete. *Cf., e.g., Dopico v. Goldschmidt,* 687 F.2d 644, 654 (holding that, where there was no formal administrative proceeding, a factual dispute as to the completeness of the administrative record precluded summary judgment prior to discovery).

At the present time, the court finds that none of the declarations that the plaintiffs have submitted need be considered in order to complete the administrative record.[6] For the foregoing reasons, the court strikes the declarations that the plaintiffs have

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[6] The court notes, as well, that the facts contained in the outside materials the plaintiffs urge it to consider would not significantly aid the court ruling on the instant question of statutory interpretation. The facts concerning the individual plaintiffs, as the plaintiff recognizes, serve merely to illustrate the legal issues before the court. *See* Plfs.' Mem. Opp. Def.'s Mot. to Strike at 3 [Doc. No. 74]. Although the plaintiffs argued at oral argument that the court should consider facts outside the administrative record for purposes of understanding the development of the Secretary's interpretation of the term inpatient, the court's ruling on the motion to strike does not prevent it from considering the Secretary's interpretive documents, nor the relevant Federal Register sections, regulations, or statutes. Counsel for the Secretary conceded at oral argument that granting the motion to strike would not prevent the court from considering the November 26, 2003 CMS memorandum, which discussed the confusion caused by the Secretary's interpretation of the term inpatient as excluding observation status. Deford Decl., Ex. C [Doc. No. 58-3].

submitted that are outside the administrative record and strikes those portions of the plaintiffs' Local Rule 56(a)1 Statement of Facts that rely on those declarations.

B. Cross Motions for Summary Judgment

1. The Secretary's Statutory Interpretation

The Medicare Act, Title XVIII of the Social Security Act, mandates that Medicare cover post-hospital extended care services at SNFs for a beneficiary who was transferred to an SNF "from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer." 42 U.S.C. § 1395x; *see also* 42 C.F.R. § 409.30(a)(1) (requiring that beneficiary was "hospitalized . . . for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge," prior to SNF admission); *id.* at § 409.10(a) ("(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term "inpatient hospital or inpatient CAH services" means the following services furnished to an inpatient of a participating hospital or of a participating CAH . . . "). Neither the statute nor the implementing regulations discuss "observation" status.

The plaintiffs challenge the Secretary's interpretation of the statutory term "inpatient" as requiring that a patient has been formally admitted to a hospital,

and classified by the hospital, as an inpatient, rather than considering the types of medical services the patient has received. The challenged interpretation is set forth in the Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 1, § 10:

> An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
>
> The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of

> treatment in each setting. Factors to be considered when making the decision to admit include such things as:
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> - The severity of the signs and symptoms exhibited by the patient;
> - The medical predictability of something adverse happening to the patient;
> - The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
> - The availability of diagnostic procedures at the time when and at the location where the patient presents. . . .

Deford Decl., Ex. E [Doc. No. 58-4]; *see also id.* at ch. 6, § 20.1 (defining "outpatient"), § 70.4.A ("Observation services are those services furnished by a hospital on the hospital's premises, including use of a bed and periodic monitoring by a hospital's nursing or other staff which are reasonable and necessary to evaluate an outpatient's condition or determine the need for possible admission to the hospital as an inpatient. . . . "); ch. 8 § 20-20.1 (stating that coverage for post-hospital extended care services requires that the beneficiary was a hospital "inpatient" for three consecutive days and that the "day of admission" is counted as an inpatient day); Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 290.1

(repeating definition of "observation services" and stating that such services usually do not exceed one day, sometimes may span two days, and "only in rare and exceptional cases" span more than two days). CMS has also issued a memorandum stating that the Office of the Inspector General had determined that days spent in "observation" status were not appropriately counted toward the three-day "inpatient" requirement for establishing SNF eligibility. CMS Memorandum (11/26/03),[7] Deford Decl., Ex. C [Doc. No. 58-3].

Although the ALJ who denied Landers' claim for SNF benefits did not specifically cite to this manual, the parties do not dispute that the requirement, that an individual be "formally admitted" to the hospital as an inpatient in order to be considered an inpatient for purposes of determining whether he or she has met the three-day hospitalization requirement for SNF coverage, reflects a longstanding CMS interpretation of the statutory requirement that an individual have been a hospital inpatient for three consecutive days before transfer to an SNF, rather than an individual error by the ALJ. Aside from their challenge to the Secretary's interpretation of the term "inpatient," the plaintiffs do not challenge any of the ALJ's legal

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[7] This memorandum also stated that SNFs and medicare beneficiaries who had previously counted observation days toward the three-day inpatient requirement, and thereby received medicare payments for SNF care, were not at fault for doing so and should not be forced to return those payments.

conclusions, and they do not challenge any of the ALJ's findings of fact. Therefore, the court focuses its review on the Secretary's interpretation, as set forth in CMS manuals, of the term inpatient, rather than on the reasoning of the individual ALJ who heard Ms. Landers' case.

2. Potential Statutory Violation

a. Ambiguity of Statute. The statute is ambiguous as to whether the term "inpatient" encompasses patients who have not been formally admitted but are receiving services similar to those given to inpatients. The statute does not explicitly define "inpatient," and the definition of this term is not clear from its context.

The amici argue that the statute unambiguously requires that the term "inpatient" include patients in the emergency room and patients on "observation" status who are later admitted as "inpatients" because the Medicare Act specifies that certain costs *preceding* admission be treated as inpatient services. *See* 42 U.S.C. 1395ww(a)(4) ("For purposes of this section, the term 'operating costs of inpatient hospital services' includes . . . the costs of all services for which payment may be made under this subchapter that are provided by the hospital . . . to the patient during the 3 days . . . immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission

(as defined by the Secretary). . . .") However, the fact that Congress included this exception does not necessarily support a conclusion that Congress intended that a patient be considered an inpatient prior to formal admission. It could also suggest that inpatient status begins with formal admission, because otherwise Congress would not have needed to spell out this exception for services rendered prior to admission. Therefore, the statute is ambiguous, and the court must next consider the appropriate level of deference to be afforded the agency's interpretation.

b. Type of Deference. The Secretary claims that his interpretation of the statutory term inpatient is entitled to the heightened level of deference described in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, courts will defer to an agency interpretation of an ambiguous statute, so long as the interpretation is based on a permissible construction of the statute. *Id.* at 842-43. *Chevron* deference applies to agency interpretations announced in "valid regulations issued through notice and comment or adjudication or in another format authorized by Congress for use in issuing 'legislative' rules." *Cmty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 138 (2d Cir. 2002) (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984) and *United States v. Mead Corp.*, 533 U.S. 218, 231-32 (2001)). Such authorization may be implied or explicit. *Mead*, 533 U.S. at 229. The Second Circuit has also held that "[l]ess formal interpretations" than either formal rulemaking or adjudication or

"legislative" rules issued in other formats that Congress has permitted

> may also be entitled to mandatory deference, depending upon to what extent the underlying statute suffers from exposed gaps in its policies, especially if the statute itself is very complex, as well as on the agency's expertise in making such policy decisions, the importance of the agency's decisions to the administration of the statute, and the degree of consideration the agency has given the relevant issues over time.

Cmty. Health Ctr., 311 F.3d at 138 (citing *Barnhart v. Walton*, 535 U.S. 212, 222 (2002)).

Where *Chevron* deference is not appropriate, respect may still be due the agency interpretation under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Under *Skidmore*, the weight to be accorded an agency's interpretation "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." 323 U.S. at 140; *see De la Mota v. U.S. Dep't of Educ.*, 412 F.3d 71, 80 (2d Cir. 2005) (quoting *Skidmore*, 323 U.S. at 140) (describing factors as "'thoroughness,' 'validity,' 'consistency,' and 'power to persuade.'"); *Cmty. Health Ctr.*, 311 F.3d at 138 (citing *Mead*, 533 U.S. at 234-35) (holding that the degree of deference depends upon "the agency's expertise, the care it took in reaching its conclusions, the formality with which

it promulgates its interpretations, the consistency of its views over them [time], and the ultimate persuasiveness of its arguments").

The Secretary argues that the interpretation at issue in this case is entitled to *Chevron* deference because it was first announced in a regulation. An earlier version of the current three-day inpatient stay regulation, promulgated in 1966, did mention "admission." It stated, "The 3-consecutive-day hospital inpatient requirement is a period of 3 consecutive calendar days beginning with the calendar day of admission even if less than a 24-hour day, and ending with the day before the calendar day of discharge." 42 C.F.R. § 405.120(c) (1966), published in 31 F.R. 10,118-19 (July 27, 1966). However, as the Secretary concedes, this rule was not subject to notice and comment, because it was promulgated before the Secretary became subject to the APA. *See* Def.'s Mem. Supp. Def.'s Mot. Summ. J. at 15 & n. 6 [Doc. No. 59-2]. In 1983, the Secretary amended the regulation to remove the reference to admission, without comment on this deletion. *See* 42 C.F.R. § 409.30(a)(1) (2006); published in 48 F.R. 12,526, 12,544 (1983).

Therefore, the fact that the 1966 regulation referred to admission shows merely consistency of interpretation, which is relevant only with respect to determining the level of deference under *Skidmore*. *See King Pharms., Inc. v. Teva Pharms. USA,* 409 F.Supp.2d 609, 615-16 (D.N.J. 2006) ("The relevance of Regulation § 1.775(a) to the Court's determination is not any persuasive value of the PTO's interpretation of

the statute as such, but rather that the PTO has for nearly twenty years maintained the position that terminally disclaimed patent may obtain a patent term extension under § 156, and, despite several amendments to § 156 in the intervening years, Congress has never acted to change the PTO's interpretation or the pertinent language of § 156"). It does not establish that the Secretary's interpretation is entitled to *Chevron* deference.

As discussed above, the Secretary's interpretation of the term "inpatient" as requiring formal inpatient admission is currently contained in the CMS Medicare Benefit Policy Manual (CMS Pub. 100-2), ch. 1, § 10, and the definition of "observation" is also in the Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 3, § 40.3. The Secretary has delegated his rulemaking authority under the Medicaid statutes to the Centers for Medicare & Medicaid Services ("CMS"). *Morenz v. Wilson-Coker*, 415 F.3d 230, 235 (2d Cir. 2005). The Second Circuit has held that "'even relatively informal' CMS interpretations warrant 'respectful consideration due to the complexity of the [Medicaid] statute and the considerable expertise of the administering agency.'" *Id.* (quoting *Cmty. Health Ctr.*, 311 F.3d at 138) (brackets in original). It has held that the State Medicaid Manual is the type of "'informal interpretation [ ]' that warrants 'some significant measure of deference.'" *Id.* (quoting *Rabin v. Wilson-Coker*, 362 F.3d 190, 197 (2d Cir. 2004) (brackets in original). It also held, in a case involving a CMS interpretation of the Medicaid

statute, that, "where a highly expert agency administers a large and complex regulatory scheme in cooperation with many other institutional actors, the various possible standards for deference begin to converge." *Cmty. Health* Ctr., 311 F.3d at 138. The Second Circuit found appropriate "some significant measure of deference to CMS's interpretation of the statute," but held that it "need not decide the exact molecular weight of the deference [it] accord[s] to CMS's position." *Id.* at 137-38 (discussing deference appropriate for interpretation in a CMS manual).

Because the court concludes that the Secretary's interpretation is correct even if it applies *Skidmore* respect, the court need not definitively resolve the question of whether the Medicare Benefit Policy Manual is subject to the more deferential *Chevron* standard.[8] For purposes of this ruling, it assumes

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[8] The court does, however, note that the manuals at issues [sic] are not legislative in nature, because the Medicare Act explicitly prohibits the Secretary from making legislative rules not promulgated as regulations:

> (1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.
>
> (2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to

(Continued on following page)

that *Skidmore* respect, and not *Chevron* deference, applies.

c. Skidmore Factors. The court has already noted CMS's considerable expertise in interpreting the Medicare statute. *See Rabin,* 362 F.3d at 198. It now turns to the *Skidmore* factors as listed in *De la Mota.* 412 F.3d at 80.

i. Thoroughness of Consideration. First, although the Secretary has not presented much specific information about the thoroughness of CMS's consideration of the inpatient definition, its inclusion in CMS manuals suggests that it was more thoroughly considered than a more informal interpretation by agency staff, such as that in *De la Mota,* 412 F.3d at 80, although not as thoroughly considered as an interpretation in a notice and comment regulation. CMS's recent call for comments on the issue, *see* 70 F.R. 29,098-29,100 (May 19, 2005), also suggests thorough agency consideration of this issue in light of changing hospital practices, even though CMS has not subsequently amended its regulations to add any definition of "inpatient" for purposes of the three-day rule. Thus, the court concludes that the agency has given fairly, but not the most, through [sic] consideration to this interpretation.

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furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. § 1395hh(a)(1) & (2).

ii. Validity of Reasoning. The Second Circuit has held that the "validity" element of the *Skidmore* analysis asks "whether an agency pronouncement is well-reasoned, substantiated, and logical." *De la Mota,* 412 F.3d at 80. The court will touch on some issues related to validity in its discussion of persuasiveness, *see* Part IV.B.2.c.iv, *infra,* but, as a preliminary matter, it finds that CMS's definition of "inpatient" is well-reasoned, substantiated, and logical. As set forth in the Medicare Benefit Policy Manual, CMS's inpatient definition explicitly leaves the decision of when to admit a patient as an inpatient to the medical judgment of the physician or other practitioner responsible for the patient's hospital care. Therefore, although situations will arise in which hospitals do not follow the Manual's instructions and wrongly delay admission for non-medical reasons, the requirement of admission itself may be seen as an administratively feasible way of determining which beneficiaries are likely to need treatment in the hospital itself for a period of twenty-four hours or more. This is consistent with the general purpose of the Medicare program, "to provide affordable medical insurance for the aged and disabled," *Furlong v. Shalala,* 156 F.3d 384, 392 (2d Cir. 1998). First, it permits the program to operate by limiting costs. In addition, patients whom medical service providers adjudge to require care in the hospital for at least twenty-four hours, and then actually spend three days in the hospital, could reasonably be expected to have more serious health problems, and thus a greater need for post-hospital SNF care, than

patients whom medical service providers adjudge as not requiring such extended care in the hospital.

iii. Consistency of Interpretation. As the plaintiffs admit, the interpretation at issue has been very consistent over time. The court will address below the plaintiffs' contention that changing hospital practices should have persuaded the Secretary to alter his interpretation. *See* Part IV.B.2.c.iv., *infra.*

iv. Power to Persuade and Lawfulness of the Secretary's Interpretation. The Secretary argues that he has validly interpreted Congress' use of the word "impatient" [sic] in the three-day hospital stay rule as referring to individuals whom hospitals have formally admitted as inpatients. The governing statute does not mandate either the interpretation advanced by the plaintiffs or by the Secretary. However, the court finds the Secretary's interpretation has the power to persuade, because it requires the inpatient admission decision to be based on medical factors, and because Congress has not amended the three-day rule over time, even as hospitals have begun to designate overnight patients as being on "observation" status before deciding whether to formally admit them as "inpatients."

The plaintiffs argue, first, that the statute's definition of "inpatient hospital services," 42 U.S.C. § 1395x(b), which lists particular types of services, shows that Congress intended the term "inpatient" to be defined with reference to the services that the hospital provides to a patient, rather than whether

the hospital has formally admitted the patient. The court disagrees. As the Secretary argues, the Medicare Act explicitly limits "inpatient hospital services" to those "items and services provided to an inpatient of a hospital." *Id.* Because Congress used the term "inpatient" to define "inpatient hospital services," the definition of the latter term does not shed light on the meaning of the former.

The plaintiffs also argue that hospitals' policies regarding inpatient admissions have changed since the drafting of the Medicare Act and since the Secretary began requiring formal admission to recognize inpatient status. They argue that hospitals have increasingly kept patients in the emergency room or placed them on "observation status" before admitting them as inpatients. In comments accompanying proposed regulations and a call for comments, the Secretary recognized that the concept of "observation status" was not envisioned at the time Congress first created the three-day inpatient requirement, and that, "over time, practice and treatment of observation time may have changed." 70 F.R. 29,070, 29,099 (May 19, 2005).[9] Changing hospital policies may sometimes result in situations that confuse beneficiaries and

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[9] This notice states, "We are aware that over time, practice and treatment of observation time may have changed; thus, the effect of not counting this observation time under the existing policy ultimately might be to restrict SNF coverage to a narrower segment of the beneficiary population than the Congress originally intended." 70 F.R. 29,099.

prevent them from receiving Medicare coverage for SNF stays, even if they have spent three days spent [sic] in the hospital. For example, a patient may remain in the same hospital bed for three full days, receiving the same, continuous treatment, yet fail to meet the three-day requirement because he was on "observation status" for the first day and was not formally admitted as an "inpatient" until the second day. Or, as was the case for Ms. Landers, a patient who began receiving treatment in the emergency room and continued receiving treatment after inpatient admission, would not have the emergency room treatment counted toward the three-day hospital inpatient requirement for SNF coverage.

If hospital admissions policies have changed drastically since Congress created the three-day hospital inpatient requirement, such changes may persuade Congress to amend that requirement to include observation status and possibly emergency room care. As of this writing, however, Congress has not passed such an amendment. This court cannot say that the Secretary's interpretation of this statute is unpersuasive in light of the language Congress used and the fact that Congress has not acted to change the Secretary's long-standing interpretation.

Next, the plaintiffs and amici argue that the Secretary's interpretation contravenes Congressional intent. As a preliminary matter, without addressing the weight it would give to any particular legislative history, the court notes that neither party, nor amici, has drawn its attention to any legislative history

concerning Congress' intended definition for the word "inpatient." Amici do cite a Federal Register notice regarding a proposed rule, in which the Secretary stated that the SNF benefit was intended to cover "those beneficiaries requiring a short-term, fairly intensive stay in a SNF as a continuation of an acute hospital stay of several days." 70 F.R. 29,070, 29,099 (May 19, 2005). In the cited notice, CMS recognized the potential unfairness created by its longstanding interpretation and the aforementioned changes in hospital admission practices. However, even if the court were to defer to the agency in divining Congressional intent, the agency's failure to change its interpretation of the term "inpatient" following the 2005 proposed rule shows that it has not concluded that such an interpretation requires it to disregard formal patient designations in favor of the inpatient definition urged by the plaintiffs and amici.

Next, amici argue that the general purpose of the Medicare Act is "to provide affordable medical insurance for the aged and disabled," *Furlong,* 156 F.3d at 392, and that the Social Security Act is to be "liberally construed and applied," *Rosenberg v. Richardson,* 538 F.2d 487, 490 (2d Cir. 1976); *see Mayburg v. Secy. of Health & Human Svcs.,* 740 F.2d 100, 103 (1st Cir. 1984). Although the plaintiffs do urge a more liberal construction than that of the Secretary, the court has found that the Medicare Benefit Policy Manual's definition of "inpatient" serves the general purposes of the Medicare Act because it ties inpatient admission to medical factors.

Although courts often look to dictionaries when defining ambiguous statutory terms, *see Smith v. United States,* 508 U.S. 223, 228-29 (1993), both the plaintiffs and defendant could find dictionary definitions that would support their preferred statutory interpretations. *Compare* Webster's Third New International Dictionary Unabridged (2002), *available at* www.mwu.eb.com ("a patient in a hospital or infirmary who receives lodging and food as well as treatment – distinguished from outpatient") *with* The American Heritage Dictionary of the American Language (4th ed. 2000), *available at* www.bartleby.com ("A patient who is admitted to a hospital or clinic for treatment that requires at least one overnight stay."). These definitions offer little guidance in resolving whether the common meaning of the word impatient [sic] implies formal admission or not.

Next, the fact that the Medicare Act specifies that certain costs preceding admission be treated as inpatient services in the context of determining coverage for hospitalization, 42 U.S.C. 1395ww(a)(4), and that the Secretary has included this exception in regulations, 42 C.F.R. § 412.2(c)(5), and the Medicare Claims Processing Manual, ch. 3, § 40.3, does not persuade to [sic] this court that Congress necessarily intended patients to be considered inpatients prior to formal admission. The rule in section 1395ww(a)(4) would not be inconsistent with a default rule that inpatient hospital services, which are limited to services rendered to inpatients, *see* 42 U.S.C. § 1395x(b), do not begin prior to admission. Congress

reasonably could have intended to cover the types of hospital services described in section 1395ww(a)(4) while still denying coverage of SNF costs where an individual was not on formal inpatient status for at least three days before transfer to an SNF. In section 1395ww(a)(4), Congress explicitly recognized that some pre-admission hospital services are bundled together with post-admission services under the term "operating costs of inpatient hospital services" for hospital billing purposes, but it did not discuss the meaning of "inpatient" as it refers to a plaintiff's status. Nothing in the text of section 1395ww(a)(4) suggests that it is intended to define the term "inpatient" for purposes of other sections of the statute. In fact, section 1395ww(a)(4) begins with the phrase, "For purposes of this section. . . ." Indeed, to the extent Congress found it necessary to amend the law in order for services rendered to patients at a time they were not yet admitted as "inpatients" to be treated as inpatient services for billing purposes, it suggests that the Secretary's interpretation of "inpatient" is correct. Therefore, the court finds that the plaintiffs' reliance on section 1395ww(a)(4) is misplaced.

The plaintiffs also urge the court to consider a group of circuit court rulings prohibiting the Secretary from treating an SNF resident, who receives solely custodial care, but no medical care, as an "inpatient of a skilled nursing facility." *E.g., Mayburg v. Sec'y of Health & Human Svcs.*, 740 F.2d 100 (1st Cir. 1984); *Levi v. Heckler,* 736 F.2d 848 (2d Cir. 1984).

In these cases, designating individual beneficiaries as inpatients of skilled nursing facilities disadvantaged them, because it permitted the Secretary to treat the entire period of time that the beneficiaries were in the SNF, combined with adjacent hospitalizations, as one continuous "spell of illness." *Mayburg,* 740 F.2d at 102; *Levi,* 736 F.2d at 848-49. Medicare covered only up to 150 days of hospital services for each "spell of illness." *Mayburg,* 740 F.2d at 102 (quoting 42 U.S.C. § 1395d(a)); *Levi,* 736 F.2d at 849 (quoting 42 U.S.C. § 1395d(a)(1)).

The Second Circuit held that to allow Medicare eligibility to turn on those factors that determined whether the family of a beneficiary needing only custodial care was able to look after the beneficiary at home rather than sending him or her to an SNF – that is, on the existence, size, financial means, and health of a beneficiary's family – "is not only illogical but also contrary to the spirit of the Social Security Act." *Levi,* 736 F.2d at 849. Both the First and Second Circuits held that an individual could be treated as an inpatient only if receiving medical treatment. *Mayburg,* 740 F.2d at 103; *Levi,* 736 F.2d. Although these cases interpret language somewhat similar to that at issue in the instant case, they raise issues different from those presently before the court. While it is true that the formal inpatient designation is often beyond a patient's control, the Secretary's inpatient definition requires that the admission decision be based on medical factors. Moreover, nothing in these cases suggests that every patient

receiving treatment from a hospital is an inpatient. They do not provide guidance on how to distinguish between inpatients and other types of patients in the context of this case.

Similarly, the fact that the Secretary at one time counted the day of discharge as a day of care for purposes of applying the three-day rule to patients transferred from Rural Primary Care Hospitals ("RPCHs") does not prevent the Secretary from interpreting the term "inpatient" to require formal admission. Until 1997, the Medicare Act required RPCHs to limit average inpatient stays to 72 hours. 42 U.S.C. § 1395i-4(f)(4) (1994) (amended 1997). To avoid denying SNF coverage to most individuals who were transferred to SNFs from RPCHs, the Secretary changed the way of calculating inpatient days for beneficiaries in this particular situation.[10] *See* 58 F.R. 30,630, 30,634-36 (May 26, 1993). However, this exception says nothing about whether a patient not formally admitted could be considered an inpatient. For similar reasons, the fact that the Secretary chose to waive entirely the three day rule for participants in the Medicare + Choice program, *see* 42 C.F.R. § 409.30(b)(2)(ii), added by 68 F.R. 50,840, 50,854 (Aug. 22, 2003), also does not persuade the court to overturn the Secretary's interpretation of the term

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[10] The Secretary terminated this exception after Congress repealed the 72-hour stay limit for RPCHs and changed their name to critical access hospitals ("CAHs"). *See* 62 F.R. 45,966, 46,008, 46,025 (Aug. 29, 1997).

"inpatient." Even if, as the plaintiffs argue, these examples show that the Secretary can effectively alter the meaning of inpatient in certain situations, they do not establish that he has to do so with respect to individuals who received care in an emergency room or on "observation" status before being admitted as inpatients.

Although the number of days of inpatient status, by any definition of "inpatient," is arguably a crude measure of the acuteness of a patient's condition or how great the need for SNF treatment is, the plaintiffs do not challenge the three-day rule itself. The plaintiffs challenge only the Secretary's failure to treat time spent receiving care in emergency rooms or on observation status, preceding formal inpatient admission, as inpatient status. Therefore, any argument that the three-day hospitalization requirement itself is irrational and/or unfair, *see, e.g.*, Br. of Am. Health Care Ass'n & Am. Med. Dirs. Ass'n as Amicus Curiae Supp. Plfs.' Mot. Summ. J. at 15-16 [Doc. No. 71], is not relevant to the issue before the court. The court does not take lightly the plaintiffs' concern that the Secretary's current interpretation of "inpatient" has created confusion among those trying to determine whether SNF care is covered or that changes in medical care have altered the circumstances under which that rule is applied. However, the plaintiffs, in effect, ask the court to make a policy judgment that is not within its purview.

In light of the considerations above, the court finds the Secretary's arguments in support of his

interpretation sufficiently persuasive to warrant respect under *Skidmore*. Although the court does not hold that the plaintiffs' proposed interpretation of the statute would be unwise, it does accord *Skidmore* respect to the Secretary's interpretation, finds it persuasive, and upholds the Secretary's interpretation.

C. Regulatory Violation

The plaintiffs also argue that the Secretary's interpretation of the term "inpatient" violates his own regulations. The regulation at issue mirrors the statute above in limiting SNF coverage to those SNF stays following transfer from a hospital at which he or she was an inpatient for at least three days. *See* 42 C.F.R. § 409.30(a)(1) (requiring that beneficiary was "hospitalized . . . for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge," prior to SNF admission); *id.* at § 409.10(a) ("(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term "inpatient hospital or inpatient CAH services" means the following services furnished *to an inpatient* of a participating hospital or of a participating CAH . . . ") (emphasis added).

This regulation, like the statute, is ambiguous because it fails to define "inpatient." In such cases, the court defers to the agency's interpretation of its own regulation, unless the interpretation is "plainly

erroneous or inconsistent with the regulation." *Auer v. Robbins,* 519 U.S. 452, 461 (1997). Here, the agency interprets inpatient status as requiring formal admission. For the reasons discussed in relation to the statute, above, this interpretation is not erroneous and not inconsistent with the regulation. The court defers to the agency and finds that the interpretation does not violate the regulation.

D. Violation of Constitutional Equal Protection

Lastly, the plaintiffs argue that the Secretary's interpretation of the term "inpatient" violates equal protection because it disadvantages one group of individuals – namely, medicare beneficiaries who stayed in a hospital for three days or more prior to transfer to an SNF but who spent less than three of those days in formal, inpatient status – as compared to another – namely, Medicare beneficiaries who were admitted as inpatients early enough in their hospital stay to have spent three days as formal inpatients prior to transfer to an SNF. The former is not a protected class, and so the Secretary's interpretation is subject to rational basis review. That is, Congress may not invidiously discriminate against a group based on characteristics that "bear no rational relation to a legitimate legislative goal." *Weinberger v. Salfi,* 422 U.S. 749, 772 (1975) (citations omitted).

In the present case, the court finds no facts, disputed or otherwise, that could permit a conclusion

that the formal inpatient admission rule discriminates based upon characteristics that bear no rational relation to a legitimate legislative goal. Although the court draws no conclusion as to whether this rule is desirable, the Secretary has identified rational reasons for it. For example, he argues that the current "inpatient" definition ties coverage decisions to physicians' medical assessments, because the manual requires physicians or other health care providers to consider medical factors in deciding whether and when to designate a patient as an inpatient. This reason relates to a legitimate, legislative goal of covering SNF care for individuals who have required significant periods of acute hospital care while also limiting Medicare's costs. Therefore, the plaintiffs' equal protection claim fails.

V. CONCLUSION

For the foregoing reasons, the court GRANTS the defendant's motion to strike **[Doc. No. 72]** to the extent specified in the text of this ruling, DENIES the plaintiffs' motion for summary judgment **[Doc. No. 55],** and GRANTS the defendant's motion for summary judgment **[Doc. No. 59].** The clerk is ordered to close the case. **SO ORDERED.**

Date at Bridgeport, Connecticut this 1st day of September, 2006.

/s/ Janet C. Hall
Janet C. Hall
United States District Judge

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

ORDER

(Filed Feb. 11, 2009)

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 11th day of February, two thousand and nine,

Docket No. 06-4921-cv

Estate of Marion Landers, as represented by its executor, Richard Landers, Marion A. Dixon and Muriel Grigley on behalf of themselves and all others similarly situated

Plaintiffs-Appellants,

V.

Michael O. Leavitt, Secretary of the Department of Health and Human Services

Defendant-Appellee.

Appellant Michael O. Leavitt, Secretary of the Department of Health and Human Services, having filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*, and the panel that determined the appeal having considered the request for panel

rehearing, and the active members of the Court having considered the request for rehearing *en banc*,

IT IS HEREBY ORDERED that the petition is denied.

For the Court:
Catherine O'Hagan Wolfe, Clerk

By: /s/ Frank Perez
Frank Perez, Deputy Clerk

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

CORRECTED ORDER

(Filed Feb. 17, 2009)

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 17th day of February, two thousand and nine,

Docket No. 06-4921-cv

Estate of Marion Landers, as represented by its executor, Richard Landers, Marion A. Dixon and Muriel Grigley on behalf of themselves and all others similarly situated

Plaintiffs-Appellants,

V.

Michael O. Leavitt, Secretary of the Department of Health and Human Services

Defendant-Appellee.

Plaintiffs-Appellants Estate of Marion Landers, as represented by its executor, Richard Landers, Marion A. Dixon and Muriel Grigley on behalf of themselves and all others similarly situated, having filed a petition for panel rehearing, or, in the alternative, for

rehearing *en banc*, and the panel that determined the appeal having considered the request for panel rehearing, and the active members of the Court having considered the request for rehearing *en banc*,

IT IS HEREBY ORDERED that the petition is denied.

For the Court:
Catherine O'Hagan Wolfe, Clerk

By: /s/ Frank Perez
Frank Perez, Deputy Clerk

130 (2) 08-1390

Supreme Court, U.S.
FILED
JAN 12 2009
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

ESTATE OF MARION LANDERS,
as represented by its executor, Richard Landers,
MARION A. DIXON, and MURIEL GRIGLEY, on
behalf of themselves and all others similarly
situated,

Petitioners,

v.

KATHLEEN SEBELIUS, Secretary of the
Department of Health and Human Services,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONERS

BRUCE VIGNERY*
KELLY BAGBY
AARP Foundation Litigation

MICHAEL SCHUSTER
AARP

601 E STREET, NW
WASHINGTON, DC 20049
(202) 434-2060
*Counsel of Record Attorneys for *Amicus Curiae*

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STATEMENT OF INTEREST[1]

AARP is a nonpartisan, nonprofit membership organization of nearly 40 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. AARP has a long history of advocating for its membership's access to affordable health care and for controlling costs without compromising quality. As many AARP members are Medicare enrollees, AARP supports their efforts to access health care provided under the program.

REASONS FOR GRANTING THE WRIT

Introduction

Medicare payment is only available for post hospitalization care in a skilled nursing facility (SNF) if the beneficiary has been an inpatient for not less than three consecutive days before discharge from a hospital and transfer to a nursing facility. 42 U.S.C. § 1395x(I) (2006); 42 C.F.R. § 409.30(a)(1) (2006). Inpatient is neither defined by statute nor regulation, but the Secretary of Health and Human Services has interpreted inpatient as requiring that

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[1] No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amicus curiae's* intention to file this brief. The parties have consented to the filing of this brief.

a patient be formally admitted to a hospital. Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services, Pub. No. 100-02, Medicare Benefit Policy Manual, ch.1, § 10 (45th rev. 2006) *available at* http://cms.hhs.gov/manuals/IOM/list/asp; *Landers v. Leavitt*, 545 F. 3d 98, 104 (2d Cir. 2008).

Medicine and the standards for patient care have changed since the creation of the Medicare program in 1965. Care that may have been provided during a three-day inpatient hospital stay in 1965 may now be provided during observation status, a status that did not exist then. Medicare beneficiaries who require acute hospitalization that involves a three-day stay, whether technically admitted as a hospital inpatient or merely held in observation status, should not be disqualified from receiving SNF coverage. Since the three-day rule was adopted, other measures have been put into place to assure that beneficiaries are not inappropriately admitted for SNF care. The Secretary's interpretation of inpatient serves only to deny payment for necessary care, not to ensure appropriateness of care.

As the Court of Appeals noted, CMS is aware that the three-day rule may be outdated. During the course of this litigation, CMS invited public comment on its policy interpretation not to count time spent in observation status towards the three-day stay requirement but then did not change its policy. According to the Court of Appeals, while "CMS's statement with respect to observation status may be less than wholly satisfying, . . . it is not so

deficient that it lacks persuasive force. . . CMS appears to be acutely aware of the changes in medical practice since the 1960s and has declined to include time on observation status because, in its view, doing so would risk undermining congressional intent [that the SNF benefit serve as a less expensive alternative to what would otherwise be the final, convalescent portion of an acute stay of several days as an inpatient at a hospital]." *Landers v. Leavitt*, 545 F.3d at 110.

CMS's decision does "lack persuasive force," *id.*, as it is at odds with the reality of modern medical practice and the underlying purpose of the three-day rule. Appellants' brief thoroughly argues that the Court of Appeals reached erroneous conclusions with regards to the analysis it conducted under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). While *amicus curiae* AARP agrees with these arguments, it seeks to inform the Court about hospital observation units, what the hospital system looked like at the time the Medicare Act was passed, and how and why observation units were developed. Considering the context within which observation units developed and how they actually operate today, AARP urges the Court to recognize that CMS's decision not to cover SNF care of patients who have been in the hospital for at least three days, but as an inpatient for only two, displays invalid, illogical reasoning and is unpersuasive.

ARGUMENT

I. OBSERVATION STATUS WAS DEVELOPED TO SAVE MONEY WHILE CONTINUING TO ALLOW ACCURATE SCREENING OF POTENTIAL ACUTE CARE ADMITTEES.

Patients often enter a hospital through the hospital's emergency room with emergency room stays averaging between two and six hours. Charles Downey, *EDTUs: Last Line of Defense Against Costly Inpatient Stays*, 10 Managed Care Magazine 44 (Apr. 2001), http://www.managedcaremag.com/archives/0104/0104.edtu.html. Before observation units, some patients were quickly treated and released. Others were released after their fears of illness were revealed to be unfounded. Many patients, however, were obviously sick, but the exact causes of their illness, and the appropriate corresponding treatment, could not be determined in a short period of time. These patients were admitted to the hospital and subsequently stayed as inpatients for an average of ten days. *See* Chapin White, *Rehabilitation Therapy In Skilled Nursing Facilities: Effects Of Medicare's New Prospective Payment System*, Health Affairs, 22, 214-223 (2003), *available at* http://content.healthaffairs.org/cgi/content/full/22/3/214 (observing "the drop in average hospital length-of-stay among the elderly from 10.7 days in 1980 to 6.1 days in 1999.") Finally, some patients were erroneously thought to need no further care and discharged to their homes. Some of these patients died needlessly. *See generally* Sean P. Collins, *et al.*, *Cost-effectiveness Analysis of ED*

Decision Making in Patients with Non-high-risk Heart Failure, 27 Amer. J. Emergency Med. 293, 295-96 (2009) (describing how patients who are discharged directly from the ED face risks of early readmission or death ["mirroring in-hospital complications or death had they been admitted"]).

Before observation units were developed, many patients initially admitted as inpatients suffered from illnesses that could be effectively treated in a less-intensive setting at a reduced cost, or only needed intensive treatment for a few additional hours. Other admitted patients, such as those complaining of chest pain, were admitted as inpatients not because they were likely to suffer a heart attack, but because of the unlikely, but horrible, consequences of being released and then subsequently suffering a heart attack. *See* Downey; *supra*, ¶ 21 (quoting the author of a textbook on observation units as stating that 4-5 percent of chest pain patients with severe myocardial infarction or ischemia were not diagnosed correctly, i.e., "missed," and consequently their "morbidity is doubled." He goes on to note that with the advent of emergency room observation units "these misses can nearly be eliminated.")

Similar dynamics are present with asthma patients. Most patients only need short, intensive treatment lasting less than a day, but there are regular but less frequent cases that require more extensive treatment only possibly through inpatient hospitalization. *E.g., see* Enrique Martinez, *et al.*, *The Observation Unit: A New Interface between Inpatient and Outpatient Care*, Am. J. Med., 110,

275-76 (Mar. 2001) (reporting that in one year 83 percent of asthma patients admitted to observation status in Cook County Hospital were discharged home within 23 hours, while the remaining 17 percent required inpatient admission, and that these rates never varied by more than 1 percent in the 3 years covered by the study.)

These examples demonstrate the dilemma. The costs associated with admitting, monitoring, and caring for inpatients were high and growing, and beds in emergency rooms were both expensive to operate and often in short supply. *See* Frederic Platt, *Reviews and Notes: Emergency Medicine: Observation Medicine; and Presenting Signs and Symptoms in the Emergency Department: Evaluation and Treatment*, Annals Internal Med., 120(7) (Apr. 1, 1994) (noting that the best "explanation for the ubiquity of medical observation units is financial. When DRGs came into being, it became economically advantageous for hospitals to label and charge differently their short-stay patients... . But the truth is that a clear and more powerful impetus exists: income available to the health care provider."); *see also* Downey; *supra*, ¶ 2 (observing emergency room visits increased 367 percent from 1955 to 1971). On the other side, the costs of non-treatment could be catastrophic. The solution that emerged was an "observation unit" – a middle-ground station.

The various types of observation units that emerged over time were, and are, so different that to refer to them as units can often be misleading. Broadly speaking, three different types of

observation units exist: 1) emergency observation/treatment units under the control of emergency room personnel where a patient can be treated further or evaluated, 2) holding units which may or may not be under the control of emergency room personnel where patients are housed pending prearranged actions such as admission or transfer, and 3) observation status beds which are beds in the inpatient area, indistinguishable from any other hospital bed, where a patient can be evaluated and/or treated for up to twenty-four hours before a decision on whether to release or admit has to be made. *See* R.M. Coffey, M.L. Barret, & S. Steiner, *Final Report Observation Status Related to Hospital Records*, 8-9, Agency for Healthcare Research & Quality, DHHS (2002), *available at* http://www.hcup-us.ahrq.gov/reports/FinalReportonObservationStatus_v2Final.pdf; *see also* TMF Health Quality Institute, *Medicare Billing Practices: Outpatient Observation vs. Inpatient Admission Patient Guidelines*, *available at:* http://hpmp.tmfhqi.net/LinkClick.aspx?fileticket=zq3tReJ88Ds%3D&tabid=521&mid=1247 (stating "Observation and inpatient are both billing statuses and not locations within the hospital. Some hospitals may have a special area just for observation while others may not.") Experts estimated that as of 2001, 45-50 percent of U.S. emergency rooms also had some form of observation unit. *See* Downey; *supra*, ¶ 13.

Within these varied settings, patients receive intensive, but quick, treatment and then will be released once the alarming symptoms have subsided (e.g., asthma patients). *See* Martinez, *supra*. Or, as already alluded, observation units can also be a

place to monitor and treat patients more cheaply than if they had either continued to take up an emergency room bed or been formally admitted as an inpatient. This was a welcome development since physicians frequently cannot diagnose with any certainty a patient's condition, or order an appropriate treatment, within the first few hours. *E.g.,* Downey, *supra*, ¶ 3 (stating observation units have developed because they "can increase the technical efficiency of hospitals [and] ... improve utilization because 80 percent of patients are found during observation to not have a serious disease and therefore can avoid hospitalization."); *see also* Lee Ann Runy, *Clinical Observation Units*, ¶ 18 (Mar. 2006), http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/2006March/0603HHN_FEA_gatefold&domain=HHNMAG (reporting that 25 percent of patients assigned to observation status are subsequently admitted as inpatients.); *see also* Martinez, *supra* (reporting that only 15 percent of patients initially admitted to observation status were subsequently hospitalized as inpatients.) As a result of this development, the medical system was able to reduce expenditures and improve patient outcomes (in some cases, e.g., chest pain, by reducing the number of those erroneously released.) *E.g.,* Michael A. Ross, *Chest Pain Observation Units Reduce Hospital Admission in People with Acute Chest Pain*, 8(4) Evidence-Based Healthcare Mgmt. 180, 180-182 (Aug. 2004) (finding there was little variation in outcomes or subsequent incidence of major events for individuals treated traditionally as inpatients and those who were placed in an observation unit, and that chest pain observation could help mitigate the

$3 billion spent annually on unnecessary admissions).

II. OBSERVATION STATUS OFTEN LENGTHENS THE TIME TAKEN TO DISCOVER HOW ILL PATIENTS ARE AND WHETHER THEY NEED ADDITIONAL CARE.

The role that observation plays today reveals the Court of Appeals' decision to be unconvincing, as it is ultimately based on the notion that CMS cannot change its policy because of a fear that a change "risks undermining Congressional intent to preserve the SNF benefit to those requiring a fairly short intensive stay in a SNF as a continuation of an acute hospital stay of several days." *Landers v. Leavitt*, 545 F.3d at 109. There may be valid reasons to initially assign a patient to observation status instead of ordering an admission; but there is no reason to treat patients assigned to observation status for one day and confirmed to need the intensive services associated with inpatient status for two additional days (a total of three days in the hospital), differently than those who spend all three days in the hospital as an inpatient.

For example, a patient arriving at the emergency room with chest pain is often quickly admitted to observation status to monitor and determine if a heart attack is imminent. Because most patients are not in such danger, determining this before they are admitted can save the hospital and CMS money. But some are in danger, and once this has been determined, these patients are

admitted as inpatients. It is not that the patient was somehow not as sick or did not need attention while she was in observation status. Instead, the hospital system has been re-engineered over time to allow this sorting mechanism to take place over a longer period of time at a lower overall cost. But patients who are admitted as inpatients right away, and a patient who is admitted to observation status for one day, confirmed to need intensive services, and then receives them over two days as an inpatient are essentially the same – patients in need of intensive services. As these are the persons Congress intended to cover in the original Medicare Act, the fact that medical practice now takes longer to sort patients into categories of (crudely speaking) the "very sick" in need of hospitalization and those "not-so-sick" who can be released, but does so more accurately and at less cost to society, should not be reason to arbitrarily deny SNF benefits to some subset of the "very sick" just because the system now takes longer to identify them.

In short, one principle function of observation status is most accurately perceived as a filtering function - a function that previously took place *as an inpatient*, but which is now done while in observation status at a lesser total cost. Regardless, anyone who spends three days in the hospital is quite obviously ill and in need of serious medical attention.

The Court of Appeals' finding that CMS decision (to define inpatient as requiring formal admission to a hospital) is justified because it advances Congressional intent to target the SNF

benefit to, apparently, the "sickest," echoes the District Court's rationale that those patients immediately admitted to inpatient status and who stay hospitalized for three days "could reasonably be expected to have more serious health problems, and thus a greater need for post-hospital SNF care, than patients whom medical service providers adjudge as not requiring such extended care in the hospital." *Landers v. Leavitt*, 2006 WL 2560297 at *9 (D. Conn. Sept.1, 2006). The error is that patients who are admitted as inpatients for at least three days *should not be compared* to patients who can be released within twenty-four hours. Petitioner and AARP do not argue that patients assigned to observation status and released within twenty-four hours should be eligible for SNF coverage, instead they argue that CMS has not identified any well-reasoned, substantiated or logical reasons as to why, in terms of post-hospital care, the fates of patients assigned to observation status, but subsequently transferred to inpatient status as their physician recognizes the severity of their illness, should be treated any differently from patients whom physicians recognize as needing inpatient services immediately.

III. OBSERVATION STATUS IS OFTEN USED AS A DEFAULT OPTION FOR BILLING PURPOSES SINCE THE PATIENT CAN RECEIVE THE SAME MEDICAL SERVICES HE OR SHE WOULD HAVE RECEIVED AS AN INPATIENT.

The objective differences between observation and inpatient status are minimal. A subset of

patients in "observation" are assigned to such a status not because the physician thinks the patient can be released within twenty-four hours, but because the physician suspects the patient should be admitted, but does not yet have enough documented information to enable such a decision to withstand the scrutiny of those who decide reimbursement matters. *See* TMF Health Quality Institute, *Medicare Patients: Observation or Inpatient Admission?*, http://www.hcpro.com/content/222633.pdf (providing a flow-chart to guide providers in decision-making relating to admissions. The chart instructs practitioners to err on the side of observation status when uncertainty remains). *Amicus curiae* suggests that this subset accounts for a disproportionate number of patients who are initially assigned to observation, but subsequently formally admitted (e.g., the plaintiffs in this case). And although physicians ostensibly employ objective medical criteria to decide whether to admit to observation or as an inpatient, once assigned a status, the patient frequently receives no different medical treatment. *See generally* Wyatt Decker, *et al.*, *A Prospective, Randomized Trial of an Emergency Department Observation Unit for Acute Onset Atrial Fibrillation*, 52 Annals of Emergency Med. 322 (Oct. 2008) (comparing differences between emergency department observation unit protocols and those employed in routine hospital admission and management. The study concluded, "An ED observation unit protocol . . . is a feasible alternative to routine hospital admission for acute onset of atrial fibrillation and results in a shorter initial length of stay").

Physicians are instructed to use observation status in this manner by a "decision-tree" guide that was produced by the TMF Health Quality Institute *under a contract with* CMS. *See* TMF Health Quality Institute, *Medicare Patients: Observation or Inpatient Admission?*, http://www.hcpro.com/content/222633.pdf ("Using outpatient observation as an alternative to admission will allow you time to determine if admission is necessary, reduce denials for unnecessary admissions and ensure that some payment is received for services rendered.")

Various publications reinforce the fact that the difference between observation and inpatient status is a billing distinction, because the medical treatment a patient receives is not different. One publication explains "the distinction between inpatient and extended outpatient observation represents a difference in billing, not a difference in medical treatment. The distinction is medically irrelevant to the ordering physician, and therefore is frequently not addressed explicitly." Administrative Consultant Services, LLC, *Bed*, I(VII), 5 & 8 (Jun. 1, 2006), *available at* http://www.acsteam.net/newsletters/medob0606.pdf. One CMS fiscal intermediary frankly states in a Local Coverage Determination (LCD), "Although in many institutions there is no difference between the actual medical services provided in inpatient and observation settings, in such cases the designation still serves to assign patients to an appropriate billing category." Riverbend Government Benefits Administrator, *LCD for Acute Care: Inpatient, Observation and Treatment Room Services (L1281)*,

¶ 2, http://www.rgbagov.com/publications/lcd/lcd-files/1281b.html.

Another CMS contractor (Lumetra, the CMS-designated Quality Improvement Organization for the state of California) makes this point more obliquely when it states that observation status is the appropriate choice when "Your patient can be evaluated or treated within 24 hours. *If you are unsure, select Observation Care*," parroting a popular "decision guide" designed to help doctors correctly chose between inpatient and observation status. Lumetra, *Hospital Observation Versus Inpatient Admission: Time to Get Your Questions Answered*, 6 (Jul. 17, 2006) (emphasis in original), *available at* http://www.lumetra.com/uploadedFiles/events/recorded-events/2006-08-08-observation-vs.-admission.pdf.

The decision guide cited by Lumetra makes two important points. First, doctors are instructed to use observation status if they think they will be able to *evaluate* a patient within 24-hours. This supports the assertion that the current observation status is frequently just a way station along the path to inpatient status, a way station that did not exist when the Medicare statute was passed because "observation" units/status did not yet exist. Previously, this evaluation was most likely performed after a patient had been formally admitted. Second, in the event that a physician is uncertain as to whether a patient should be admitted, they are instructed to choose observation status as the default. It is important to note that physicians will frequently choose observation status

if any uncertainty exists as to reimbursement for their services. *See* TMF Health Quality Institute, *TMF Review & HPMP Update*, 1 (Dec. 2004), *available at* http://www.tmf.org/update/archive/1204Update.pdf ("Handling care in outpatient observation when appropriate ... reduces denials for unnecessary admissions *and ensures that some payment is received.* The care can be the same as care provided to an inpatient, but how that care is reimbursed is different—*outpatient observation is strictly a billing status.*") (emphasis added)

Since the care a patient receives is frequently no different whether in observation or inpatient status, basing the decision of whether to cover post-hospital SNF care on location simply does not make sense. In addition, CMS, through decision guides produced and promulgated by its contractors, instructs physicians to resolve any uncertainty in favor of observation status. *See* Lumetra, *supra*. CMS's definition of "inpatient" is presumably valid because it leaves the decision to the supposedly objective, "medical judgment" that ostensibly lies behind a physician's decision to admit as an inpatient or into observation. Reality is that placing a patient in observation is as likely a result of a lack of a bed, a lack of diagnostic accuracy, or a concern for billing as it is a product of objective medical decision making. *See* TMF Health Quality Institute, *Review Related Frequently Asked Questions*, ¶¶ 11-13, http://casereview.tmf.org/ReviewRelatedFAQs/tabid/506/Default.aspx (admitting that TMF would interpret a physician's written order to "admit *to* observation" differently from "admit *for* observation," with the former being interpreted as observation

status, while the latter is deigned an inpatient, implicitly acknowledging that the coverage of a patient's SNF care hinges upon a doctor's (perhaps careless) choice of a preposition.)

CONCLUSION

For the foregoing reasons, this Court should grant petitioners' writ of certiorari.

Respectfully submitted,

Bruce Vignery*
Kelly Bagby
AARP Foundation Litigation

Michael Schuster
AARP

601 E Street, NW
Washington, DC 20049
(202) 434-2060

Attorneys for *Amicus Curiae* AARP

*Counsel of Record